

Bond University

MASTER'S THESIS

Breastfeeding in an urban population

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Breastfeeding in an urban population

Bond University

Thesis title

Breastfeeding in an urban population

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RN, RM, IBCLC

Submitted in total fulfilment of the requirements of the degree of

Master of Science by Research

2010

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Breastfeeding in an urban population

Declaration

This thesis is submitted to Bond University, in fulfilment of the requirements for the Degree of Master of Science by Research. This thesis represents my own work and contains no material which has been previously submitted for a degree or diploma at this university or any other institution, except where due acknowledgement is made.

Signed:

Date:

Author's contribution to Cochrane Review: 'Interventions for preventing mastitis after childbirth'

Maree Crepinsek is the primary author as well as the contact author for this Cochrane Systematic Review. The conception, design and co-ordination of both the protocol and review were conducted by Maree Crepinsek. Maree also provided a clinical perspective for the review, as well as writing the review in Review Manager. Dr Neil Smart provided support as a co-author, providing general advice on the writing of both the protocol and review. Maree Crepinsek and Dr Neil Smart independently reviewed all articles found in the search, initially by title and abstract. Full texts of articles selected were then reviewed by Maree Crepinsek and Dr Neil Smart for inclusion into or exclusion from the review. Linda Crowe is the second author who provided a clinical perspective and general advice on the review. Maree Crepinsek and Linda Crowe independently extracted the data from the selected articles for analysis. Keryl Michener provided support as a librarian writing search strategies, carrying out searches and locating papers used as background research evidence.

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Breastfeeding in an urban population

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Breastfeeding in an urban population

support throughout this period in our lives. You have been my rock; I could not have done this without your love.

I would like to dedicate this work to all mothers – past, present, and future – who have the important role of nurturing future generations.

Breastfeeding in an urban population

Thesis abstract

Introduction

Despite the many health benefits of breastfeeding, exclusivity and duration rates fall short of the World Health Organisation guidelines. This body of work is an examination of breastfeeding exclusivity and duration in an urban population.

Aims

This thesis aimed to investigate the breastfeeding initiation rates of women in the Gold Coast region of Queensland, to report on the breastfeeding exclusivity and duration rates of a sample of breastfeeding women from this population, to describe their knowledge of mastitis, and to review published interventions for the prevention of mastitis in breastfeeding women after childbirth.

Methods

This longitudinal study investigated a population of women who delivered their infants at the Gold Coast hospital in 2008. Firstly, the prevalence of breastfeeding upon hospital discharge in a cohort of postpartum women was observed and reported. From this population, a subgroup cohort was recruited and followed for a period of six months or until they weaned their infant. The subgroup study was designed to provide cross-sectional data about breastfeeding exclusivity and duration within an Australian urban population, as well as to compare breastfeeding women's knowledge of mastitis within the clinical definition. Finally, a Cochrane systematic review examined the published literature on interventions for the prevention of mastitis after childbirth.

Breastfeeding in an urban population

Results

Findings suggest that breastfeeding exclusivity and duration rates observed are comparable with rates from other national studies including survey data. Prevalence data showed that 87.5% of women discharged from hospital exclusively breastfeeding. The cross-sectional subgroup showed participants exclusively breastfed for a mean of 95.27 ± 73.40 days, while the mean breastfeeding duration was 125.36 ± 70.47 days. The responses to the questionnaires demonstrated that the majority of women have a minimal understanding of mastitis and its treatment. Participants reported that their first option when seeking information on mastitis was their mother or family and friends, followed by their general practitioner. The Cochrane Systematic Review identified the need for better quality trials and interventions that are more vigorous in the prevention of mastitis following childbirth. The trials published to date produced no statistically significant findings or benefits from any interventions designed.

Conclusions

Ongoing research is required into improving breastfeeding duration rates so that they reach recommended levels. Further research into effective interventions for the prevention of mastitis in the postpartum period is required to reduce the prevalence of mastitis in breastfeeding women.

Breastfeeding in an urban population

Abbreviations

Acronym	Description
ABA	Australian Breastfeeding Association
ANHS	Australian National Health Survey
BF	Breastfeeding
BFHI	Baby Friendly Hospital Initiative
BSES-SF	Breastfeeding Self Efficacy Scale – Short Form
CDCU	Central Data Collection Unit
EL/CS	Elective Caesarean Section
EM / CS	Emergency Caesarean Section
GCHSD	Gold Coast Health Service District
GCH	Gold Coast Hospital
HSCQ	Health Statistic Centre Queensland
NHMRC	National Health & Medical Research Council
PDCS, QLD	Perinatal Data Collection Centre Queensland
QLD	Queensland
SIDS	Sudden Infant Death Syndrome
SPSS	Statistical Package for the Social Sciences
UNICEF	United Nations Children’s Fund
VD	Vaginal Delivery
WHO	World Health Organisation

Breastfeeding in an urban population

Table of Contents

<i>Bond University</i>	1
<i>Thesis title</i>	1
<i>Breastfeeding in an urban population</i>	1
<i>Author's contribution to Cochrane Review: 'Interventions for preventing mastitis after childbirth'</i>	3
<i>Acknowledgement</i>	4
<i>Thesis abstract</i>	6
<i>Introduction</i>	6
<i>Aims</i>	6
<i>Methods</i>	6
<i>Results</i>	7
<i>Conclusions</i>	7
<i>Abbreviations</i>	8
<i>Table of figures</i>	10
<i>Table of tables</i>	13
<i>Table of appendices</i>	13
<i>Thesis inspiration</i>	16
<i>Thesis overview</i>	17
<i>Chapter 1 Literature review – Australian and global breastfeeding overview</i>	20
<i>Study aims</i>	38
<i>Chapter 2 Methods</i>	39
<i>Breastfeeding definitions</i>	40
<i>Study 1: Prevalence of breastfeeding at the Gold Coast Hospital</i>	41
<i>Study 2: Breastfeeding duration and exclusivity in an urban population</i>	42
<i>Study 3: Cochrane systematic review - Intervention for the prevention of mastitis after childbirth</i>	44
<i>Methodology flow chart of the studies used in this thesis</i>	45
<i>Chapter 3 Prevalence of breastfeeding at the Gold Coast Hospital</i>	46
<i>Introduction</i>	46
<i>Methods</i>	48
<i>Results</i>	51
<i>Conclusions</i>	55

Breastfeeding in an urban population

<i>Chapter 4 Breastfeeding duration, exclusivity and knowledge of mastitis in an urban population</i>	57
<i>Introduction</i>	57
<i>Methods</i>	58
<i>Results</i>	68
<i>Conclusions</i>	87
<i>Chapter 5</i>	89
<i>Study 3 Cochrane systematic reviews - ‘Intervention for the prevention of mastitis after childbirth’</i>	89
<i>Background</i>	89
<i>Methods</i>	89
<i>Results</i>	90
<i>Chapter 6 Discussion</i>	92
<i>Introduction</i>	92
<i>Summary</i>	92
<i>Limitations of the first two studies in this thesis</i>	101
<i>Summary of recommendations from studies</i>	102
<i>Appendices</i>	106
<i>Appendix 1: Questionnaire</i>	106
<i>Appendix 2: Breastfeeding Self-Efficacy Scale (BSES)</i>	109
<i>Appendix 3: Cochrane Systematic Review</i>	110
<i>References</i>	111

Table of figures

<i>Figure 1: Outline of thesis chapters</i>	19
<i>Figure 2: Schema defining the varied definitions of exclusive and partial breastfeeding rates.</i>	41
<i>Figure 3: Flow chart briefly describing the methods used in each of the three studies for this thesis.</i>	45
<i>Figure 4: Flow chart outlining the design of Study 1, ‘Prevalence of breastfeeding at the Gold Coast Hospital’ and the tools used to collect data for this study.</i>	48
<i>Figure 5: Illustration of the age distribution of the women who gave birth at the Gold Coast Hospital in 2008 as reported in Study 1.</i>	51

Breastfeeding in an urban population

Figure 6: Illustration of the infant feeding choice made by the women who gave birth at the Gold Coast Hospital in 2008 as reported in Study 1. 52

Figure 7: Reported number of women who had a vaginal delivery (VD) including instrumental / assisted deliveries (i.e. vacuum, forceps), elective caesarean section (EL/CS) or emergency caesarean section (EM/CS) birth at the Gold Coast Hospital during the data collection period for the 'Prevalence of breastfeeding study' (n=1093), grouped by the woman's parity. 53

Figure 8: Flow chart illustrating an overview of the methodology used for Study 2 'Breastfeeding duration, exclusivity, and knowledge of mastitis in an urban population'. 59

Figure 9: Frequency distribution of the number of children (parity) of the women from the 'Breastfeeding exclusivity and duration study' (n=200). 70

Figure 10: Survival curve of breastfeeding duration grouped by parity for a six month period of the women from Study 2 'Breastfeeding exclusivity, duration and knowledge of mastitis in an urban population' (n=200). 76

Figure 11: Survival curve for breastfeeding exclusivity grouped by parity for a six month period of the women from Study 2 'Breastfeeding exclusivity, duration and knowledge of mastitis in an urban population' (n=200). 76

Figure 12: Breastfeeding trends at one month from several available sources (see Footnote below) This figure illustrates the comparison of breastfeeding rates at 1 month as reported from available sources including the women from Study 2 'Breastfeeding exclusivity, duration and knowledge of mastitis study in an urban population' (n=200). 78

Figure 13: Breastfeeding Self Efficacy Scale – short form (BSES-SF) score distribution. Data collected from the participants during the initial interview when recruited into Study 2 - 'Breastfeeding exclusivity, duration and knowledge of mastitis study in an urban population' (n=200). 80

Figure 14: Scatter plot – illustrating the relationship between the Breastfeeding Self Efficacy Scale - short form (BSES-SF) score and the number of days that women

Breastfeeding in an urban population

exclusively breastfeed (maximum of 182 days of exclusive breastfeeding reported) from Study 2 participants (n=200). 81

Figure 15: Scatter Plot – illustrates the relationship between the Breastfeeding Self Efficacy Scale - short form (BSES-SF) score and the total duration of breastfeeding reported (maximum of 182 days duration of breastfeeding reported) from Study 2 participants (n=200). 82

Figure 16: Frequency distribution of responses for question (1) reporting the women's knowledge of mastitis: What is mastitis? 84

Figure 17: Frequency distribution of responses for question (2) reporting the women's knowledge of mastitis: How do you treat mastitis? 85

Figure 18: Frequency distribution of responses for question (3) reporting the women's knowledge of mastitis: How did you find this information? 86

Breastfeeding in an urban population

Table of tables

<i>Table 1: Global view illustrating the percentage of infants (at six months) exclusively breastfed (2006).⁽⁴⁾</i>	21
<i>Table 2: Australian National Health Survey, reporting the age of breastfeeding mothers in 2001.⁽³⁷⁾</i>	27
<i>Table 3: Profile of the women from who gave birth at the Gold Coast Hospital, including their type of delivery, parity, and method of feeding when discharged from hospital during the period of data collection for the 'Prevalence of breastfeeding' study in 2008.</i>	54
<i>Table 4: Infant feeding methods reported by Queensland health in 2006, and the Gold Coast Hospital in 2006 (Perinatal Data Collection) & in 2008 (Data from Study 1).</i>	55
<i>Table 5: Comparison of the women's parity between our two studies 'Prevalence of breastfeeding study' and 'Exclusivity and duration of breastfeeding study' in 2008.</i>	69
<i>Table 6: Frequency of categorical variables for education and occupation as reported on the women in Study 2.</i>	71
<i>Table 7: Breastfeeding intention data, collected from the women in Study 2 – 'Breastfeeding exclusivity, duration, and knowledge of mastitis study in an urban population'.</i>	72

Table of appendices

<i>Appendix 1: Questionnaire</i>	106
<i>Appendix 2: Breastfeeding Self-Efficacy Scale (BSES)</i>	109
<i>Appendix 3: Cochrane Systematic Review</i>	110

Breastfeeding in an urban population

Publications

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Presentations

Crepinsek M, Crowe L, Michener K, Smart N (2008). Interventions for preventing mastitis after childbirth, Cochrane systematic review (Protocol) published May 2008.PHCRED. GP & PHC Research, Conference 'Driving Change' Melbourne, Wednesday 15th – Friday 17th July 2009

Crepinsek M, Crowe L, Michener K, Smart N (2008). Interventions for preventing mastitis after childbirth, Cochrane Systematic Review (Protocol) published May 2008.Health in transition, research for the future, the 4th international conference on community health nursing research August 2009 Adelaide South Australia.

Crepinsek M, Crowe L, Michener K, Smart N (2008). Interventions for preventing mastitis after childbirth, Cochrane Systematic review (Protocol) published May 2008. PHCRED, research fellows meeting November 2008 Brisbane QLD Australia.

Crepinsek M, Smart N, Brodribb W, Van Driel M. The effect of mastitis on breastfeeding exclusivity and duration. Research Design & Statistics Research Proposal Seminar, Bond University Gold Coast, Australia. 2008.

Posters

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Crepinsek M, Smart N, Brodribb W. Self-management versus Usual Care of Mastitis Following Childbirth: A Randomised Control Trial. ACNN 3rd Annual Neonatal Conference Gold Coast April 2008.

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Breastfeeding in an urban population

Thesis inspiration

As a clinical midwife and lactation consultant in hospitals and private practice, sharing many women's breastfeeding experiences and challenges has provided me with knowledge and an interest in breastfeeding and complications of lactation. This experience has led me to pursue breastfeeding research.

While at the University of Southern Queensland (USQ), the experience I gained as a researcher provided insight into investigating women's experiences and complications of lactation. The research I conducted at USQ consisted of two studies. The first involved setting up a telephone support service for women in the postpartum period. This service provided women with weekly telephone support and consultation with an experienced lactation consultant during the first month postpartum. Part of the support service also involved triaging women to health services for support when required. Most referrals were for breastfeeding related complications. The second study involved interviewing women who had experienced extraordinary breastfeeding complications but had continued to breastfeed.

As a result of conducting these studies, and through experience and observations as a lactation consultant in private practice, it became apparent that mastitis was a common breastfeeding problem. Women would often only seek help with this debilitating disease in the later stages, instead of earlier when the outcomes and recovery could have been more favourable. These observations led me to investigate the prevalence of mastitis, along with what can be done to reduce its incidence and improve the duration and exclusivity of breastfeeding.

Breastfeeding in an urban population

Thesis overview

This thesis consists of four parts. Chapters 1, 3, 4 and 5 outline the four main elements including the literature review and three studies. Chapter 2 outlines the research design and methodology.

Following the review of relevant literature, Chapter 1 provides an overview of conditions that affect breastfeeding initiation, exclusivity, and duration trends on a global, national, and state level. This chapter then discusses complications of lactation, mastitis in particular, and concludes with the aims of the study.

Chapter 2 gives an overview of the methodology of each of the three studies in this thesis. A comprehensive outline of the methodology used for each study is detailed in the relevant chapter.

Chapter 3 covers '*Prevalence of breastfeeding at the Gold Coast Hospital*'. This study collated breastfeeding and limited demographic information from women who birthed at the Gold Coast Hospital between January 2008 and April 2008. The data collected were used to compare maternal age, parity, mode of feeding and the type of delivery against national and international breastfeeding rates. Data on breastfeeding exclusivity, duration and knowledge of mastitis were not available for the women in this study, which led to Study 2 (covered in Chapter 4).

Chapter 4 details '*Breastfeeding duration, exclusivity, and knowledge of mastitis in an urban population*'. Firstly, this provides cross-sectional data about breastfeeding exclusivity and duration rates within an Australian urban population and, secondly, it

Breastfeeding in an urban population

compares the women's breastfeeding knowledge of mastitis with the clinical definition. Thirdly, Chapter 4 benchmarks the Gold Coast breastfeeding data with both global and national statistics. During this study the participants were asked three exploratory questions about their knowledge of mastitis, and findings from the review of these questions has led to the third study in this thesis

Chapter 5 is a Cochrane Systematic Review of the published literature on the prevention of mastitis following childbirth up until November 2010 titled '*Interventions for preventing mastitis after childbirth*'.

Finally, the results and limitations of these studies are discussed, as well as recommendations. An outline of this thesis has been summarised in Figure 1.

Breastfeeding in an urban population

Thesis outline briefly describing each chapter

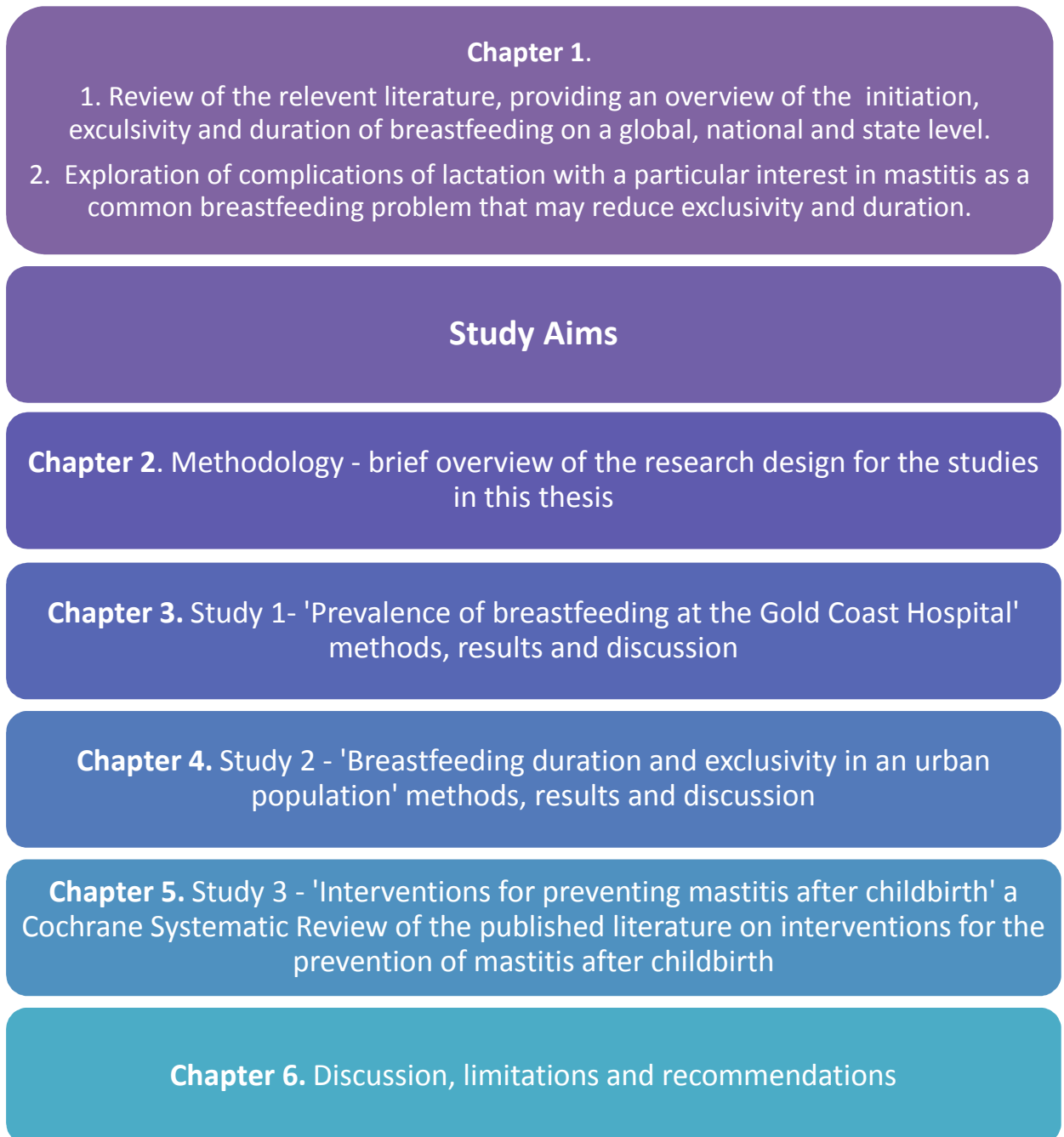


Figure 1: Outline of thesis chapters

Chapter 1 Literature review – Australian and global breastfeeding overview

Introduction

The importance of breastfeeding for the health and wellbeing of infants and mother is documented in both this literature review and other published articles; however, this research was motivated by the factors that affect breastfeeding exclusivity and duration, along with an exploration into complications of lactation (mastitis in particular).

The literature review detailed in this chapter compared global breastfeeding practices with Australia, Queensland, and the Gold Coast region. Along with the comparison of global practices, factors were explored that influence women's breastfeeding decisions, including complications of breastfeeding. Mastitis is one of the most common complications of lactation that affects breastfeeding decisions including exclusivity and duration,^(1, 2) and therefore will be a major component of this thesis.

Breastfeeding recommendations and benefits

Australian national breastfeeding targets continue to fall short of the guidelines as reported in 2002, by the World Health Organisation (WHO) and the Australian National Health and Medical Research Council (NHMRC).^(1, 2) WHO recommends that infants be exclusively breastfed for six months with a further recommendation of continuing breastfeeding until at least 2 years of age with the addition of appropriate complementary foods. In comparison, the NHMRC recommends that women continue

Breastfeeding in an urban population

to breastfeed until their infants are at least 12 months of age.^(1, 2) Exclusive breastfeeding provides the mother and infant with both short and long-term benefits.⁽³⁾ There has been considerable discussion with regard to the optimal length of time a mother should fully breastfeed her infant. The United Nations Children's Fund (UNICEF) has compiled global breastfeeding rates. Table 1 illustrates breastfeeding figures at six months of age in 2006 in a number of countries and regions⁽⁴⁾, demonstrating that neither developed nor developing countries are able to meet with the recommendations of the WHO.

Table 1: Global view illustrating the percentage of infants (at six months) exclusively breastfed (2006).⁽⁴⁾

Region	Percentage of infants at six months exclusively breastfed (2006)
Sub- Saharan Africa	30%
Middle east/North Africa	26%
South Asia	45%
East Asia/ Pacific	32%
Latin America/Caribbean	*
Central Europe/Russian Republics, and Baltic States	19%
Industrialized countries	*
Developing World	37%
Developed countries Norway and Sweden	70-80%
European countries as well as USA, Canada and Australia	Ranged from 20% to 50%
* Percentages could not be calculated due to missing data from > 25% of countries in the region. ⁽⁴⁾	

Breastfeeding provides benefits to infants, mothers, families, and communities. The improved nutrition, immunological, psychological, economical and environmental benefits that breastfeeding provides are well documented.⁽⁵⁾ Breast milk provides

Breastfeeding in an urban population

benefits as well as protection against conditions such as gastroenteritis, respiratory infections and allergies.⁽⁶⁾ Extensive scientific research reports that infants who are not breastfed are predisposed to many health complications in later life, including high blood pressure, obesity, non-insulin dependent diabetes and ischaemic heart disease.⁽⁵⁻⁸⁾

Breastfeeding trends and changing attitudes

Breastfeeding in Australia has gradually changed from the 1900s to the present day. With increased medical intervention in everyday life issues, including childbirth and breastfeeding, more doctors and health professionals are involved in the treatment of childbirth and breastfeeding.^(9, 10) Improvement in health practices has brought about a decrease in infant /maternal mortalities in the last century; however, along with the modification of cow's milk and the introduction of commercial formulas in the mid 1900s, there has been a decline in the number of women who breastfeed. This has been reinforced by the increase in availability and popularity of commercial milks endorsed by health professionals.⁽⁹⁾ The introduction of formulas has reduced infant mortality for those infants previously fed cow's or goat's milk, but has negatively affected breastfeeding rates.⁽¹⁰⁾

Since the introduction of commercial formula in the 1970s, there has been a decline in breastfeeding initiation and duration in both developed and developing countries.^(3, 11) In the early 1970s, Australia demonstrated higher breastfeeding initiation rates than other developed countries; however, it was estimated that only 40-45% of women were breastfeeding when discharged from Australian hospitals at this time.^(11, 12) In

Breastfeeding in an urban population

order to address this problem, steps were taken by the Commonwealth Department of Health in 1979 to introduce policies on food and nutrition.⁽¹¹⁾ Australia further strengthened its policy on breastfeeding practices by becoming a signatory to the WHO International Code for the Marketing of Breast-Milk Supplements in 1981.⁽¹³⁻¹⁵⁾

Historically, breastfeeding women have sought the accumulated knowledge and support of other mothers, especially their peers.⁽¹⁰⁾ In the mid 1950s and early 1960s, women became more empowered and knowledgeable, forming breastfeeding support groups. The emergence of peer groups such as La Leche League International and the Nursing Mothers Association Australia [now known as the Australian Breastfeeding Association (ABA)] in the mid 1960s provided women with breastfeeding support.⁽²⁾ These groups continue today providing education and support for women.

The Baby Friendly Hospital Initiative

The decline in breastfeeding rates prior to the 1990s was cause for concern; therefore, a worldwide effort to protect, promote, and support breastfeeding was initiated. In 1991, the WHO and UNICEF jointly developed 'The Baby Friendly Hospital Initiative' (BFHI).⁽¹⁶⁾ The BFHI international project aims to create a health care environment that provides the best start in life for every infant born.⁽¹⁶⁾ BFHI, in conjunction with WHO and UNICEF, identified the need for education of health professionals and mothers who intend to breastfeed to improve breastfeeding management.⁽¹⁶⁻²⁰⁾

World governing bodies recognised that to improve breastfeeding rates, policies and standards by which health care practice would be governed when caring for women in the postpartum period should be developed.⁽²¹⁾ The Baby Friendly Hospital Initiative

Breastfeeding in an urban population

(BFHI) was launched to transform health care policies and to restore breastfeeding as the natural and normal practice for nurturing infants.⁽²²⁾ BFHI is thus a strategy to encourage the implementation of the "Ten Steps to Successful Breastfeeding" to protect, promote and support breastfeeding.⁽²³⁾

Accredited "baby friendly" hospitals endeavour to give women consistent, accurate advice to reduce breastfeeding problems experienced in the early postpartum days, including nipple damage, low milk supply and confusion about breastfeeding.⁽²²⁾ The BFHI initiative has been successful in improving the initiation of breastfeeding in most developed countries.⁽²⁴⁾ For example, an improvement in the initiation of breastfeeding from 47 to 80% was reported in 2009 in Ireland. Australia has a comparatively high initiation of exclusive breastfeeding on discharge from hospital (87%), but has a low rate of breastfeeding exclusivity for the recommended six months of age.^(22, 24, 25) This drop in breastfeeding rates from discharge to six months possibly indicates that educating and supporting women with regards to their breastfeeding decisions needs to continue beyond their discharge from hospital.

Breastfeeding practices in Australia

Both the Australian National Health Survey (ANHS) in 2001 and the Queensland State Health and Perinatal Statistics Survey for 2001 found that 87% of infants were breastfed when discharged from hospital.⁽²⁶⁾ These surveys however also reported a steady decline in the number of infants receiving any breast milk up to the age of six months.⁽¹²⁾ In 2001, only 48% of infants aged six months were breastfed with only 23% of children breastfed by age one and 1% being breastfed by age two.⁽¹⁾

Breastfeeding in an urban population

In 2003 Queensland Health established exclusive breastfeeding targets to be achievement by 2008. These included that at least 60% of infants would be exclusively breastfed for the first three months, and that at least 50% of infants would be exclusively breastfed for the first six months.⁽²⁷⁾ In 2006-2007, Queensland Health conducted a study (Infant Nutrition Project 2006-2007 Measurements of exclusive breastfeeding) aimed to determine the prevalence of breastfeeding, particularly exclusive breastfeeding, in three South East Queensland Health Service Districts.⁽²⁷⁾ This study reported that the majority of mothers in the districts that participated in this study were not meeting the targets for exclusive breastfeeding for the first six months as recommended by Queensland Health.⁽²⁷⁾ Reported data show that 38% of infants in the cohort were exclusively breastfed at two months of age, and only 9.5% at five months of age.⁽²⁷⁾ Therefore even with guidelines and targets set out by governing bodies, women are continuing to breastfeed for less than the minimum recommended length of time. This finding demonstrates that an exploration into factors affecting women's breastfeeding decisions is required.

Factors that influence breastfeeding decisions

Many factors affect the initiation and duration of breastfeeding, including socio-demographic, biomedical, support and psychosocial issues.^(25, 28, 29) The literature suggests that improving breastfeeding initiation and duration rates not only provides maternal and infant advantages but also has environmental and economical benefits for both the health care systems and individual families.^(25, 28-32)

Breastfeeding in an urban population

Common breastfeeding issues that women experience when initiating lactation such as poor attachment and positioning of the infant at the breast, along with inadequate emptying of the breast may inhibit the establishment and maintaining of adequate lactation while breastfeeding.^(25, 28, 29, 30) These breastfeeding issues often lead to complications including damaged nipples, breast engorgement and mastitis. Breastfeeding issues such as these may lead to complications that hinder establishing and maintaining breastfeeding exclusivity and duration.^(25, 28, 29, 30) As with other known complications of lactation, mastitis is reported to influence a woman's breastfeeding decision. Leading authorities have recognised modifiable variables that influence breastfeeding exclusivity and duration.

Both modifiable and non-modifiable factors affect breastfeeding duration and exclusivity. Several non-modifiable demographic factors such as maternal age, marital status and education level are possible predictors of breastfeeding exclusivity and duration.^(33, 34) Studies observe that older married women who are more educated and have a higher socio-economic status breastfeed for longer.^(35, 36) Given that these factors are difficult to modify, there is little hope of changing them to improve breastfeeding exclusivity and duration.^(28, 35, 36) Identifying modifiable variables alternatively, could lead to the development and evaluation of supportive interventions resulting in more women initiating and continuing to breastfeed. One such variable is the maternal perception of insufficient milk supply that often leads to formula supplementation and a decrease in breastfeeding levels. Breastfeeding confidence has also been identified as a modifiable variable for breastfeeding duration.^(33, 34)

Breastfeeding in an urban population

Non-Modifiable Variables

Both national and international studies have referred to increasing maternal age as a predictor for increased breastfeeding duration.^(35, 37-40) A positive association with exclusive breastfeeding at both 2 and 5 months and maternal age was reported in the Infant Nutrition Project 2006-2007 in Queensland. This study also reported that mothers with partners were more likely to exclusively breastfeed at 2 months.⁽⁴¹⁾ Australian studies have found that women over the age of 25 years were more likely to continue breastfeeding their infants for between six and twelve months.⁽⁴²⁻⁴⁷⁾ In addition, the Australian National Health Survey (ANHS) reported that women aged over 30 were more likely to be breastfeeding at six and 12 months than those aged between 18 and 29, as seen in Table 2.⁽¹²⁾

Table 2: Australian National Health Survey, reporting the age of breastfeeding mothers in 2001.⁽³⁷⁾

Maternal age	% of breastfeeding mothers at six months	% of breastfeeding mothers at twelve months
18-29 years	38%	14%
> 30 years	54%	28%

A prospective cohort study of 522 women from five hospitals in America also found that age was a important demographic factor in determining breastfeeding duration.⁽⁴⁸⁾ In addition, a Korean study that examined factors affecting the rate and duration of breastfeeding from interviews, reported that women over the age of 35

Breastfeeding in an urban population

years breastfeed for longer than younger women.^(49, 50) However, maternal age was not found to be a major factor in a woman's decision to breastfeed.⁽⁴⁹⁻⁵¹⁾ Maternal age would therefore appear to influence the duration of breastfeeding but not the initiation.

Studies that looked at marital status as a predictor of breastfeeding duration have shown that women who are married or in a defacto relationship, in contrast to single mothers, tend to have higher breastfeeding initiation rates.⁽⁵¹⁾ The importance of a supportive relationship, in contrast to the isolation experienced by some single mothers, is conducive to breastfeeding success.⁽⁵²⁾ In 2007, a study that evaluated the associations between maternal psychological status and intended breastfeeding duration found that there was a positive association between the breastfeeding duration outcome and marital status.⁽⁵³⁾

Maternal education has been shown to be considerably associated with breastfeeding success.⁽⁴⁸⁾ In 2001, the Australian National Health Survey (ANHS) established that women with associate diplomas or higher education were more likely to breastfeed. Several national and international studies have reported that the higher the woman's level of education, the greater the breastfeeding initiation rate and the longer the duration of breastfeeding.^(12, 42, 43, 54)

The dilemma women face over whether, and how, to combine breastfeeding and work has been identified as a confounding factor when it comes to infant feeding methods.⁽⁵⁵⁾ Working mothers find the decision to return to work and to continue breastfeeding to be difficult, often affecting the exclusivity and duration of

Breastfeeding in an urban population

breastfeeding.⁽⁵⁵⁾ A recent study reported that employment in routine jobs with less favourable working conditions, compared to higher managerial and professional occupations, may reduce the duration of exclusive breastfeeding.⁽⁵⁵⁾

Levels of breastfeeding initiation and duration vary between primiparous and multiparous women. In a study by Humenick in 1998,⁽⁵⁶⁾ primiparous women who were encouraged by health care professionals to provide supplements for their infants often weaned prematurely, whereas multiparous women with previous positive breastfeeding experiences were more likely to act independently of professionals' advice.⁽⁵⁶⁾ In contrast, multiparous women who had negative breastfeeding experiences, even with professional support, tended to have lower breastfeeding initiation and duration rates.⁽⁵⁶⁾

Breastfeeding exclusivity and duration has been strongly related to parity and previous breastfeeding experiences.^(42, 43) In 1990, Ford and Lobbok⁽⁵⁷⁾ found that breastfeeding duration increased with parity by one half month per child. More recent studies reported that mothers with previous breastfeeding experience had higher initiation and duration rates.^(56, 58) A large study conducted in the Netherlands in 2001 reported that, while a higher level of education was important in relation to breastfeeding success, parity was seen to be the most decisive factor in breastfeeding duration.⁽⁵⁹⁾ In summary, the combined factors of breastfeeding experience, age of mother and parity can influence breastfeeding exclusivity and duration; however, as seen in the Infant Nutrition Project 2006–2007, the rates of exclusive breastfeeding reported are substantially lower than the targets set by Queensland Health for 2008.⁽⁴¹⁾

Breastfeeding in an urban population

Modifiable Variables

Maternal attitude is one potentially modifiable variable associated with breastfeeding confidence. A positive and persistent attitude has been identified as supportive of successful breastfeeding.⁽⁶⁰⁻⁶³⁾ Creedy and colleagues, in 2003, reported that women who were confident in their ability to breastfeed were likely to breastfeed for longer.⁽⁶⁴⁾ Higher levels of self-efficacy and persistence were also reported as important predictors for breastfeeding duration.⁽⁶⁴⁾ Breastfeeding self-confidence is having confidence in oneself when choosing a course of action to be the best or most effective. In contrast, breastfeeding self-efficacy is the belief that one has the power to produce the desired effect and is capable of performing in a competent manner to attain certain goals.⁽⁶⁵⁾

Women are more inclined to breastfeed for longer when they report a higher breastfeeding self-efficacy in the antenatal period. In contrast, women with a reported lower self-efficacy in the antenatal period are more inclined to partially breastfeed or formula feed^(61, 62) and are more likely to wean before two weeks postpartum.⁽⁶⁶⁻⁷⁰⁾

Women found to have difficulties establishing lactation were also reported to have lower levels of self-efficacy in contrast to women who breastfed for six months and beyond, and were reported to wean prematurely.⁽⁶¹⁾ Women who breastfed for four months and beyond were more likely to enjoy and be satisfied with their breastfeeding experience.^(61, 71-74) Stress and anxiety are factors also known to affect breastfeeding success. Mothers who are separated when the infant is admitted to special care nursery or intensive care may experience stress and anxiety that influences their

Breastfeeding in an urban population

breastfeeding experience.⁽⁷⁵⁾ Recent studies have shown that highly motivated mothers of low birth weight or premature infants breastfeed for longer, suggesting that mothers understand the importance of breast milk for their infants.⁽⁷⁶⁾ Negative attitudes, lack of experience breastfeeding previous infants, and prematurity have been seen to have detrimental effects on breastfeeding success.⁽⁷⁵⁾ Mothers of healthy full term infants are more likely to initiate breastfeeding, but maternal attitude will influence breastfeeding continuation.^(30, 34)

A study by Meyerink and Marquis highlighted the importance of support from family and friends for breastfeeding women.⁽⁷⁷⁾ Support was seen to impact on the increased probability of mothers initiating breastfeeding.⁽⁷⁷⁾ The significance of a woman's partner, family and peers are shown to influence breastfeeding by giving women the encouragement and help needed to breastfeed successfully, hence nurturing maternal confidence. A number of studies have shown peer support to have a positive effect on breastfeeding women's experiences.^(28, 29, 77) Face-to-face and telephone-based peer support groups show a noteworthy difference in breastfeeding initiation rates.^(78, 79) However, telephone-based and peer support studies has been reported to have no effect on breastfeeding duration.⁽⁸⁰⁾

The importance of supportive partners and the effect on breastfeeding success has been reported in several studies.^(28, 48) In Western countries, husbands and partners who support and encourage breastfeeding are reported to influence the woman's breastfeeding choices and behaviour.^(10, 81, 82)

Breastfeeding in an urban population

While many factors influence a woman's decision to stop breastfeeding, perceived low milk supply, maternal and infant complications, and mastitis are the most frequent reasons women report.^(28, 29, 71, 72, 83, 84) Blyth reported in 2002 that the main reason given for premature weaning related to complications of lactation.⁽⁶¹⁾ These included insufficient milk supply, maternal factors (including mastitis, nipple trauma and fatigue), and infant factors (including premature infants, sucking disorders and tongue-tie).^(74, 85) Breastfeeding inconvenience, establishing lactation, infant dependency as well as hospital breastfeeding policies and practices were seen to influence lactation decisions.⁽⁶¹⁾

Antenatal and postnatal education about breastfeeding issues and complications helps to address common problems in the prenatal period, providing women with strategies and tools with which to manage. Along with encouraging and supporting early skin-to-skin contact for mothers and infants, early initiation of feeding and maternal support has been reported to enhance breastfeeding success.⁽⁸⁶⁾ Commonly encountered problems known to influence a woman's decision about continuing to breastfeed or prematurely wean include sleep deprivation and insufficient time for oneself.^(29, 87, 88)

Approximately 35% of women who wean early report insufficient milk supply as the primary reason, although most mothers have sufficient milk to nourish their infants.^(29, 87-91) Perception of low milk supply is often reported early in the postpartum period, well before milk supply has been established and is one of the most commonly professed problems associated with breastfeeding exclusivity and duration.⁽⁸⁸⁾ Appropriate education may reduce the apparent gap between perceived and actual

Breastfeeding in an urban population

milk supply and thus reduce the number of women who wean prematurely.⁽⁹¹⁾ Other women are concerned about the quality of their breast milk as well as the quantity.⁽⁸⁸⁾ These problems are often confused with other parenting issues such as settling techniques and normal infant behaviour.^(28, 29, 86-88)

Mastitis

Mastitis is a significant breastfeeding complication experienced by lactating women.⁽⁹²⁾ The definition of mastitis varies throughout the literature. The symptoms commonly reported when defining mastitis include an infection of the breast causing a fever of > 38.5 and a red tender area in the breast. Diagnosis of mastitis ranges from self-diagnosis and management to clinical diagnosis by a health care professional. The variation in the definition and diagnosis of mastitis presents several problems when reviewing the literature due to the inconsistencies of reported presentations and measures of the disease. In order to clarify the meaning of mastitis, the following definition of mastitis was used in this study:

‘an inflammatory condition of the breast, which may or may not be accompanied by infection’^(7, 93)

There are two main causes for lactation mastitis, the first resulting from milk stasis and the second from direct microbial infection. Milk stasis, which is the stagnation of milk in the breast, is the primary cause of lactation mastitis, due to inefficient milk removal. This form of mastitis may be accompanied by bacterial infection and may be due to several reasons such as poor attachment of the infant to the breast, ineffective suckling, restricted frequency or duration of feeds, blockage in milk ducts, and

Breastfeeding in an urban population

overabundant milk supply.⁽⁹⁴⁾ The second cause of mastitis is most commonly due to bacterial infection from an interruption in the integrity of the nipple, caused by trauma during feeding and often a result of incorrect attachment.^(2, 95, 96)

Mastitis is seen as a continuum of disease, resulting in a series of phases from non-infective inflammation of the breast to infection that may lead to abscess formation. *Staphylococcus aureus* is the most common microorganism found.⁽⁹⁵⁻⁹⁷⁾ Mastitis can present bilaterally but most commonly unilaterally with breast pain, redness, and swelling which may be associated with systemic symptoms such as fever aches and pains.^(98, 99) Women may experience recurrent mastitis with one or with consecutive infants.⁽¹⁰⁰⁾ The varying presentation of severity or prevalence of this disease results in a multitude of problems for both breastfeeding women and health care professionals.

Mastitis has a detrimental effect on exclusivity and duration of breastfeeding.^(71, 72) The prevalence of mastitis worldwide varies depending on the definition used, the reliability of reporting and on the country in which the study was conducted.⁽¹⁰⁰⁾ International studies following participants for between three and 12 months have reported the incidence of mastitis to be between 5% and 33%, while the recurrence of mastitis is between 6.5% and 8.5%.^(71, 72, 83, 101, 102) Mastitis is most commonly experienced in the earlier stages of lactation with between 74 and 95% of the episodes being experienced in the first three months of breastfeeding.⁽¹⁰⁰⁾ Australian studies have reported that the incidence of mastitis in the first six months is between 15 and 20%.⁽¹⁰³⁻¹⁰⁷⁾

Breastfeeding in an urban population

Although mastitis is a considerable complication of breastfeeding, and a common reason for weaning, there has been little published work in this area of lactation.⁽⁹²⁾

While studies have reported that exclusive breastfeeding with unrestricted access of the infant to the breast ensures adequate breast emptying and reduces the risk of milk stasis.⁽⁸⁴⁾ Studies have further explored the concept of breastfeeding and bed sharing (co-sleeping) of infants and parents ^(108, 109). This practice is a choice some breastfeeding women make to assist unrestricted access of the infant to the breast while sleeping, facilitating breast emptying and further reducing the risk of milk stasis ^(108, 109). Additional well-known breastfeeding practices that decrease the risk of mastitis include proper attachment and correct positioning of the infant at the breast. These practices reduce nipple damage, as well as pain and hesitation when breastfeeding, thereby reducing the risk of engorgement, milk stasis and mastitis. ^(83, 100)

One of the problems highlighted in the literature is that women report breastfeeding advice given by health care professionals is often conflicting and unhelpful. ⁽¹¹⁰⁾ A proportion of breastfeeding women who develop mastitis receive incorrect management advice from health care professionals. Two of the most common misconceptions regarding the management of mastitis are to rest the affected breast during the episode of mastitis and to wean from the breast ^(19, 111, 112). This advice is contrary to the more appropriate advice of ensuring frequent emptying of the breast to prevent milk stasis, with breastfeeding being the most efficient means of achieving this. ⁽¹¹⁵⁾ Breast-feeding is generally not harmful to the infant during episodes of mastitis and speeds resolution of the infectious and /or inflammation process. ⁽¹¹³⁻¹¹⁶⁾

Breastfeeding in an urban population

The research to date highlights the importance of prevention and management of mastitis to reduce the incidence of breast abscess and improve maternal health.⁽¹⁰⁰⁾

An Australian study found that women who reported a history of mastitis with a previous child were more likely to have mastitis with the current baby.⁽¹⁰⁵⁾

Breastfeeding education and breastfeeding management techniques, such as breast massage, frequency of breastfeeding, alternating breasts at each feed, use of hot/cold packs, correct positioning and the use of cabbage leaves are all interventions that have been trialled in the management of mastitis.⁽¹¹⁴⁻¹¹⁶⁾

Conclusion

Breastfeeding is a global issue for communities and governments that affect both women and their infants on many levels. Despite identifying factors that influence the initiation of breastfeeding and the importance of breastfeeding to both mother and infant, there continues to be sub-optimal duration of exclusive breastfeeding in both developing and developed countries. Modifiable factors such as maternal attitude, support, breastfeeding knowledge, and experience affect duration and exclusivity of breastfeeding.

National and international researchers, as well as governing bodies, have outlined guidelines that support and promote breastfeeding, strongly advocating breastfeeding as being the best practice by which to feed infants.^(7, 93, 117-121) Complications of lactation remain an important factor resulting in decreased breastfeeding exclusivity and duration rates. One of the most common complications is mastitis. The debilitating effect that mastitis has on lactating women has been explored, identifying common

Breastfeeding in an urban population

misdiagnoses, and the problems associated with misinformation and poor management. It is therefore important to explore and identify pathways for improvement with these health issues, such as well-designed research studies to provide answers.

This chapter reviewed breastfeeding exclusivity and duration from a state, national and global perspective. Findings from the literature review influenced the formation of the following studies, which were designed to measure the prevalence of breastfeeding exclusivity and duration in an urban population.

Breastfeeding in an urban population

Study aims

The aims of this study were to identify the prevalence of breastfeeding of the women who gave birth at the Gold Coast hospital between January and April 2008, and to report on the breastfeeding exclusivity rates and duration of a sample of breastfeeding women from this population. Further to this, participants' knowledge of mastitis was reported and the published interventions for the prevention of mastitis in breastfeeding women after childbirth were reviewed.

Several research questions were generated from these study aims:

1. Is the initiation of breastfeeding amongst women who birth at the Gold Coast Hospital consistent with national breastfeeding initiation rates?
2. What are the exclusivity rates and duration of breastfeeding in this population of women, and are they consistent with national figures?
3. Do the women who breastfeed in this population have an understanding of mastitis consistent with the clinical definition of mastitis?
4. Are interventions to reduce the incidence of mastitis effective in the postnatal breastfeeding period?

Key words: Breastfeeding, mastitis, exclusivity, duration and interventions.

Chapter 2 Methods

Introduction

The literature review in Chapter 1 identified that there is limited breastfeeding practices research, which explores exclusivity and duration rates as well as maternal knowledge of mastitis. This chapter will describe the methods used to answer the research questions posed above. It describes two main areas of this research, firstly to qualify breastfeeding definitions used throughout this work. This issue was evident when reviewing the literature, and highlighted the inconsistencies in the reporting of breastfeeding practices. Therefore, in order to identify the quantity of breastfeeding undertaken by the women in this body of work, it was necessary to define varying degrees of breastfeeding.

The second area addressed in this Chapter provides a brief overview of the methodology and research designs used in each study. The three studies conducted in this thesis have been designed to address the research aims; firstly to assess the prevalence of breastfeeding in an Australian urban population, secondly to quantify the breastfeeding exclusivity and duration rates in this population and, thirdly, to explore the level of mastitis knowledge in this population of breastfeeding women.

Breastfeeding in an urban population

Breastfeeding definitions

On review of the literature, it was identified that Australian and international governing bodies promote breastfeeding as the optimal infant feeding practice.⁽¹²²⁾ In contrast to this international consensus, there is little consistency in defining levels of breastfeeding practices.⁽¹²²⁾ This has impacted considerably on the research that underpins breastfeeding policy and the monitoring of breastfeeding rates.⁽¹²²⁾ The lack of clarity within definitions has impeded the interpretation of data linking breastfeeding with infant health, nutrition, growth and development.

The use of the word 'breastfeeding' alone is insufficient to describe the many types of breastfeeding practices. For instance, full breastfeeding can be divided into categories of 'exclusive' and 'almost exclusive'. Similarly, partial breastfeeding can be differentiated into 'high', 'medium' and 'low' levels.⁽¹²²⁾ To address the issue of breastfeeding definition for this study, and to maintain a level of continuity, the following scheme has been adopted and modified from Labbok and Krasovec (1990) 'schema for breastfeeding definitions'.⁽¹²³⁾

Breastfeeding in an urban population

Definition of breastfeeding

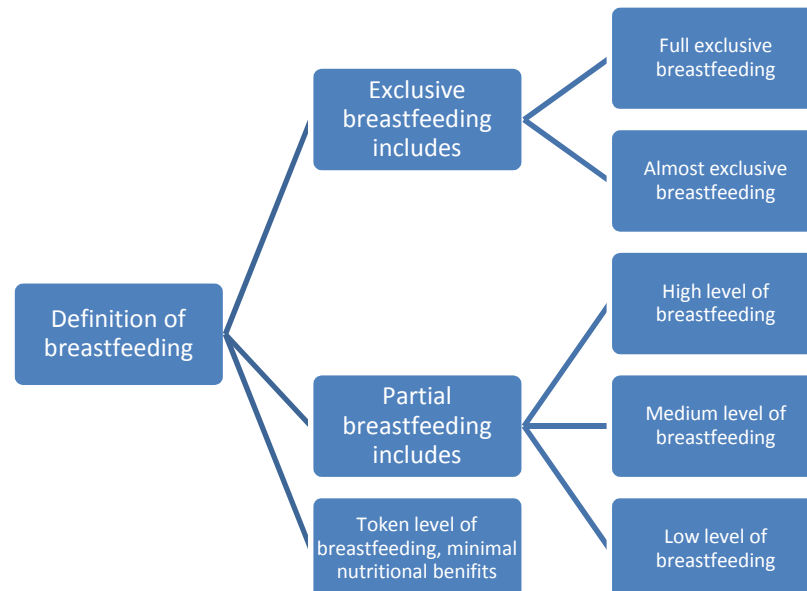


Figure 2: Schema defining the varied definitions of exclusive and partial breastfeeding rates.

Methodology

In order to collect data to address the study aims, both qualitative and quantitative data collection methods were used. This enabled the collection of a range of information from more than one source and at different time intervals, as required for these studies.

Study 1: Prevalence of breastfeeding at the Gold Coast Hospital

Study 1 quantified the prevalence of breastfeeding amongst women who birth at the Gold Coast Hospital and investigated if they were consistent with the national breastfeeding initiation rates. This study also explored the feeding choices of the

Breastfeeding in an urban population

women who delivered within the Gold Coast Health Services District between January and April 2008.

Data were collected on maternal demographics, as well as infant feeding method at the time of hospital discharge. The monthly quantitative data collected from the Gold Coast Health Service District Data Collection Service on this population of women, included, maternal age, and number of births per month, parity, and type of delivery for the Gold Coast Hospital. These details provided information that allowed the calculation of breastfeeding prevalence at this hospital, as well as a descriptive analysis of this population. From this information, a profile of the women that could be recruited into Study 2 was constructed.

Study 2: Breastfeeding duration and exclusivity in an urban population

Study 2 measured breastfeeding exclusivity and duration rates and identified the women's breastfeeding intention, breastfeeding confidence and knowledge of mastitis. The questionnaires designed for this study were a result of previous research experience and perusal of similar research designs and questionnaires. These questionnaires were scrutinised by several senior research academics and a content expert. This longitudinal study recruited a cohort of breastfeeding women from Study 1 population, who were followed via telephone interviews for a period of six months or until they weaned their infants. The study consisted of two phases:

Phase 1 – initial interview to collect demographic data as well and information on breastfeeding intention, knowledge of mastitis and breastfeeding confidence. This data was collected in hospital prior to discharge.

Breastfeeding in an urban population

Phase 2 – monthly telephone follow-up interviews, conducted to collect data on breastfeeding exclusivity and duration.

A questionnaire was developed for each phase of the study, with extensive input from senior academic staff, as well as consultation with a subject matter expert, Dr Wendy Brodribb.

Study 3: Cochrane systematic review - Intervention for the prevention of mastitis after childbirth

Study 3 reviewed the published literature for interventions to reduce the incidence of mastitis, and their effectiveness in the postnatal breastfeeding period. This systematic review of the published literature evaluated randomised controlled trials of interventions for the prevention of mastitis after childbirth using the Cochrane protocol outlined. (Copy of this published review has been attached see Appendix 3).

Breastfeeding in an urban population

Methodology flow chart of the studies used in this thesis

Methods

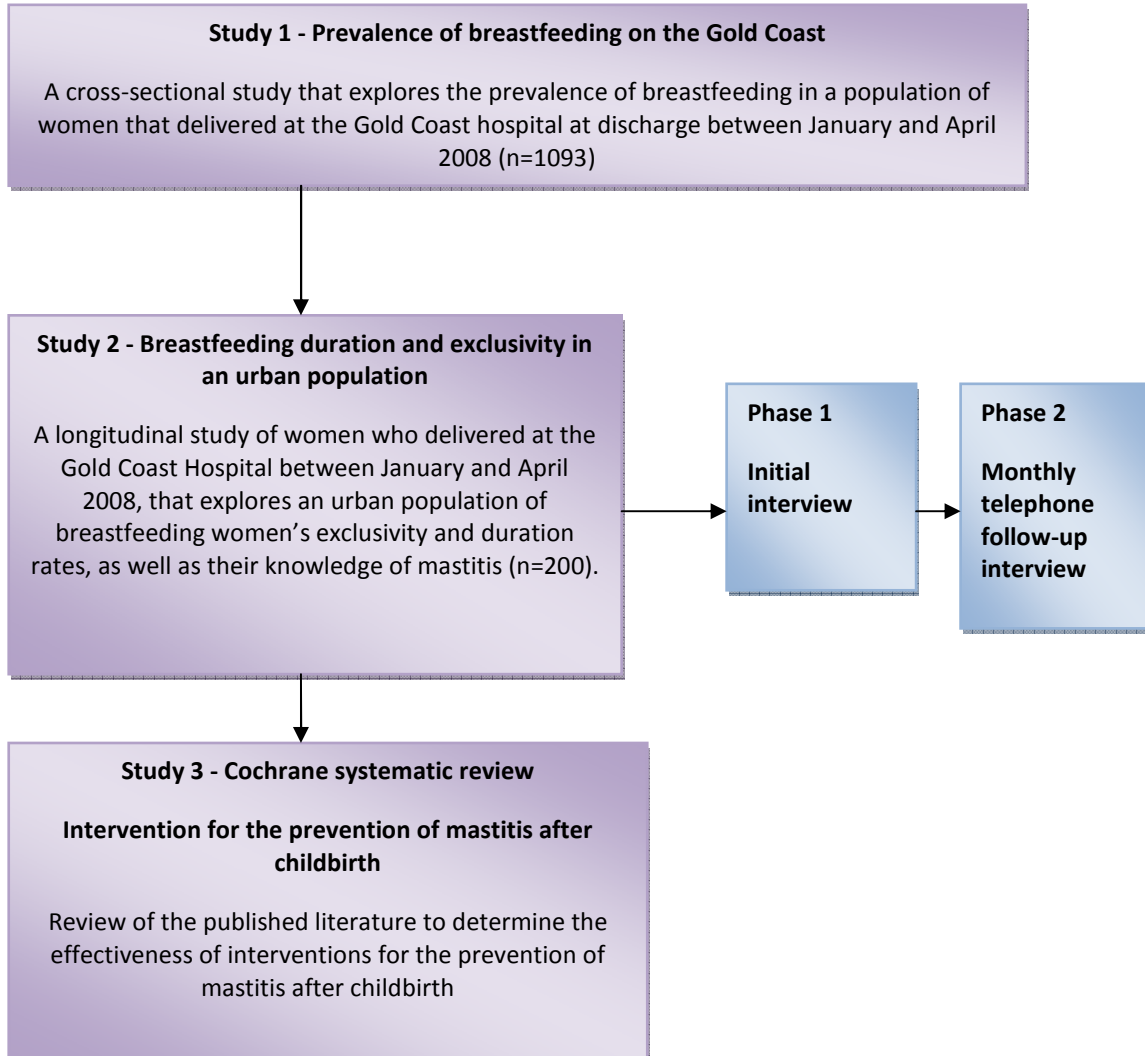


Figure 3: Flow chart briefly describing the methods used in each of the three studies for this thesis.

Chapter 3 Prevalence of breastfeeding at the Gold Coast Hospital

Introduction

This chapter addresses the first aim of this study, describing and discussing the initiation of breastfeeding amongst women who birth at the Gold Coast Hospital. It also compares the findings with national breastfeeding initiation rates. The data collected in this research study reveal the feeding choices of women who birthed at the Gold Coast Hospital during the time of the study, thereby reporting the prevalence of breastfeeding in this urban population.

National breastfeeding prevalence

Reporting of breastfeeding prevalence varies. As previously reported in chapter 1 the Australian National Health Survey in 2001 reported that 87% of infants aged between 0-3 years had at some stage obtained nutrition from breast milk. This is very similar to the breastfeeding rate in 1995 (86%).⁽²⁶⁾ In 2006 Queensland Health reported a breakdown of breastfeeding practices, with 82.6% of women exclusively breastfeeding on discharge from hospital, and 4.7% both breast and formula feeding.⁽²⁷⁾ Current Australian urban breastfeeding data are limited; however, there have been two research projects conducted in Queensland, which reported breastfeeding prevalence. These include the 'Toowoomba infant feeding support service project - a longitudinal needs analysis of breastfeeding behaviours and supports in the Toowoomba region' and the 'South East Queensland Health Infant Nutrition Project 2006-2007 Measurements of exclusive breastfeeding'. Therefore, the results of this study were

Breastfeeding in an urban population

instrumental in developing a database of breastfeeding practices of women who delivered in southeast Queensland.

Births at the Gold Coast hospital

The Australian Bureau of Statistics reported that in 2006 there were 265,900 births registered in Australia with 52,665 of these infants born to Queensland mothers. In Queensland in 2007, the number of births increased to 61,249 births, 16% more births than in 2006. This was the largest increase of all states and territories. The Gold Coast region had 4711 live births collectively between hospitals, with 2560 (54%) of these at the Gold Coast hospital.⁽¹²⁴⁻¹²⁶⁾

The design of this population health study was to assess the breastfeeding exclusivity and duration of an Australian urban population. When reviewing breastfeeding practices on the Gold Coast, it became apparent that there were no published data on breastfeeding duration and exclusivity of patients that gave birth at the Gold Coast hospital. As the Gold Coast is a rapidly growing urban population it was an ideal setting, with a sufficient number of births, in which to recruit participants for this study.

As identified in Chapter 1, data are limited on the prevalence of breastfeeding in Australia. In order to identify the prevalence of breastfeeding in an Australian urban population, such as the Gold Coast, it was necessary to conduct a quantitative, population-based cohort study. This study collected data from women who delivered at the Gold Coast hospital during the period from the 8th January to the 30th April 2008.

Breastfeeding in an urban population

Methods

The aim of this quantitative study was to determine breastfeeding prevalence in an Australian urban population. Figure 3 is a flow chart that outlines the design of Study 1 'Prevalence of breastfeeding at the Gold Coast Hospital'.

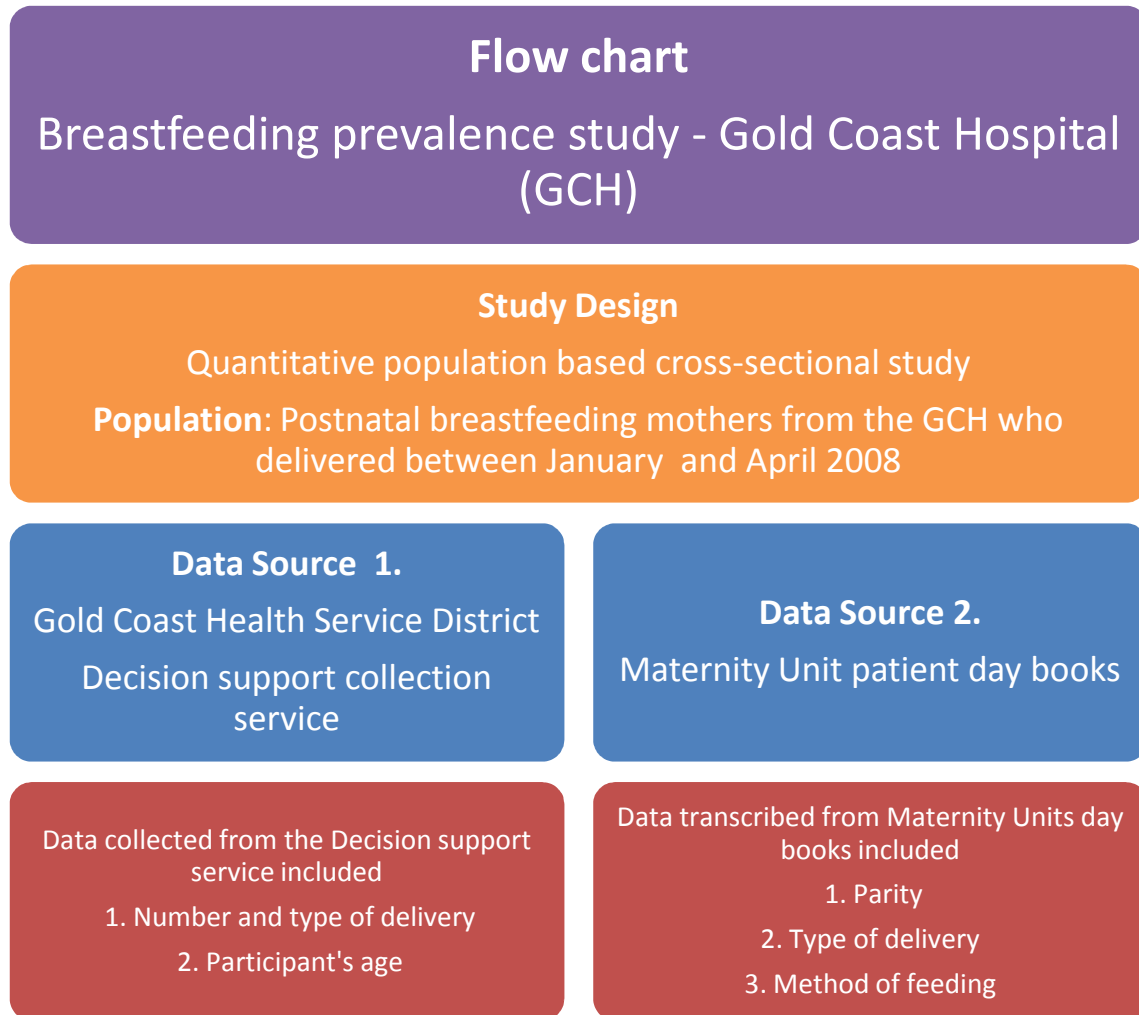


Figure 4: Flow chart outlining the design of Study 1, 'Prevalence of breastfeeding at the Gold Coast Hospital' and the tools used to collect data for this study.

Breastfeeding in an urban population

Ethics approval

Prior to commencement of this study, ethics committee approval to conduct this research was obtained from both Bond University (Protocol number RO606) and Gold Coast Health Service District (Research Proposal 200771).

Subjects and Setting

Data were collected from all women who delivered their infants at the Gold Coast hospital between January and April of 2008. Following ethics approval, both the executive and maternity unit staff at the Gold Coast Hospital (GCH) were consulted about the method of data collection to ensure minimal disruption to the maternity unit. Data pertaining to maternal age, feeding choices and type of delivery were collected from the facility's Central Data Collection Unit (CDCU). Data were also collected on a monthly basis from the maternity unit patient daybooks, which are used by the clinical staff to monitor new admissions/ discharges, room allocation, treatment and management of the patients while in hospital. All data collected were de-identified to protect patient identity.

Transcription of patient daybooks and data collected from CDCU

In order to collect the data for this research study, it was necessary to collect data from these independent sources. Due to the method of storage of this information, data collected for the purpose of this study were sourced from separate departments within the hospital. The following data of the women who birthed at the hospital were collected on a monthly basis from the CDCU via email: total number of births for the

Breastfeeding in an urban population

month, maternal age, type of delivery (vaginal delivery, elective caesarean section, or emergency caesarean section) and parity (primiparous or multiparous). Data on maternal feeding methods on discharge (breastfeeding, formula feeding, or both) were collected from the maternity unit's patient daybooks. These data were not electronically stored, so relevant information from the patient day books were manually transcribed and entered into an SPSS database for management and analysis. Due to the different data sources, it was not possible to link the data or, consequently, conduct inferential analysis.

Despite the limitations of this method of data collection, the fact that the numbers of women from the two data sources corresponded displays the accuracy of the collected data. This data set provided a population from which a subgroup of women was recruited for a study of breastfeeding exclusivity, duration and the understanding of mastitis and appropriate treatment.

Statistical analyses

Quantitative data were analysed using SPSS version 17.0 for Windows.⁽¹²⁷⁾ Descriptive analyses reported the mean, standard deviation and percentage of the demographic data. A Chi-Square test of independence was conducted for maternal age and parity as well as the type of delivery and parity. Statistical significance was considered to be at 5%.

Breastfeeding in an urban population

Results

The total number of births during the study period was 1112 (includes multiple births), and the number of women participants was 1093. The mean age of women was 29 \pm 5.8 years.

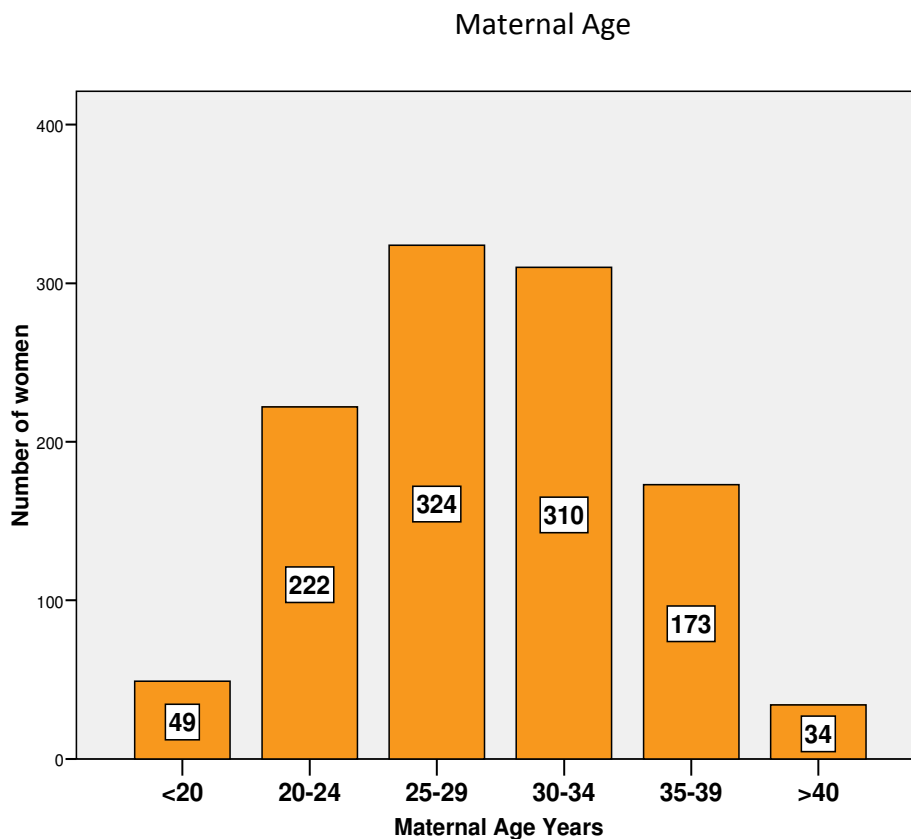


Figure 5: Illustration of the age distribution of the women who gave birth at the Gold Coast Hospital in 2008 as reported in Study 1.

Of the 1093 women included in the study, 517 (47.3%) were primiparous and 576 (52.7%) were multiparous. Data collected on the method of infant feeding at discharge from hospital has been illustrated in the Venn diagram below (see Figure 6), which reports that 956 of the women were exclusively breastfeeding (BF), 96 were formula feeding (FF) and 41 were partially breastfeeding their infants.

Breastfeeding in an urban population

Prevalence of exclusive breastfeeding versus partial and formula feeding

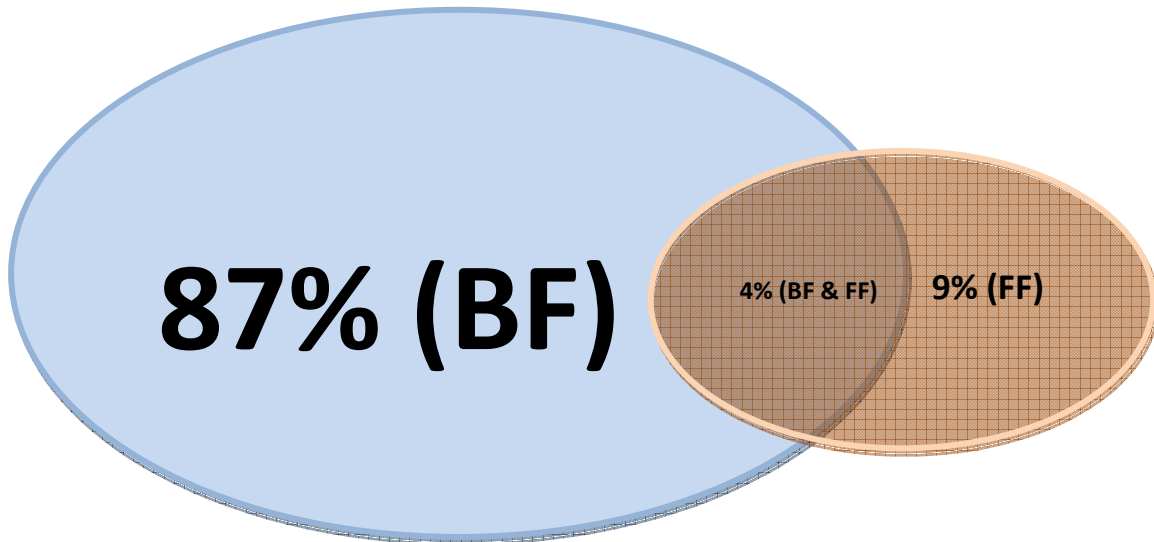


Figure 6: Illustration of the infant feeding choice made by the women who gave birth at the Gold Coast Hospital in 2008 as reported in Study 1.

Footnote: Breastfeeding (BF), Formula feeding (FF).

The number of deliveries conducted at the GCHS ranged from between 257 and 309 per month with a mean of 273.3 ± 24.30 . Overall, there were 780 (71.4%) vaginal deliveries (VD) including instrumental / assisted deliveries (i.e. Vacuum, forceps), 159 (14.4%) emergency caesarean sections (EM C/S) and 154 (14.1%) elective caesarean sections (EL C/S).

Breastfeeding in an urban population

Figure 7 illustrates the women's methods of delivery grouped by their parity. The majority of women had vaginal deliveries 780 (71.4%) including instrumental vaginal deliveries (vacuum/ forceps) of the 1096 participants in this study.

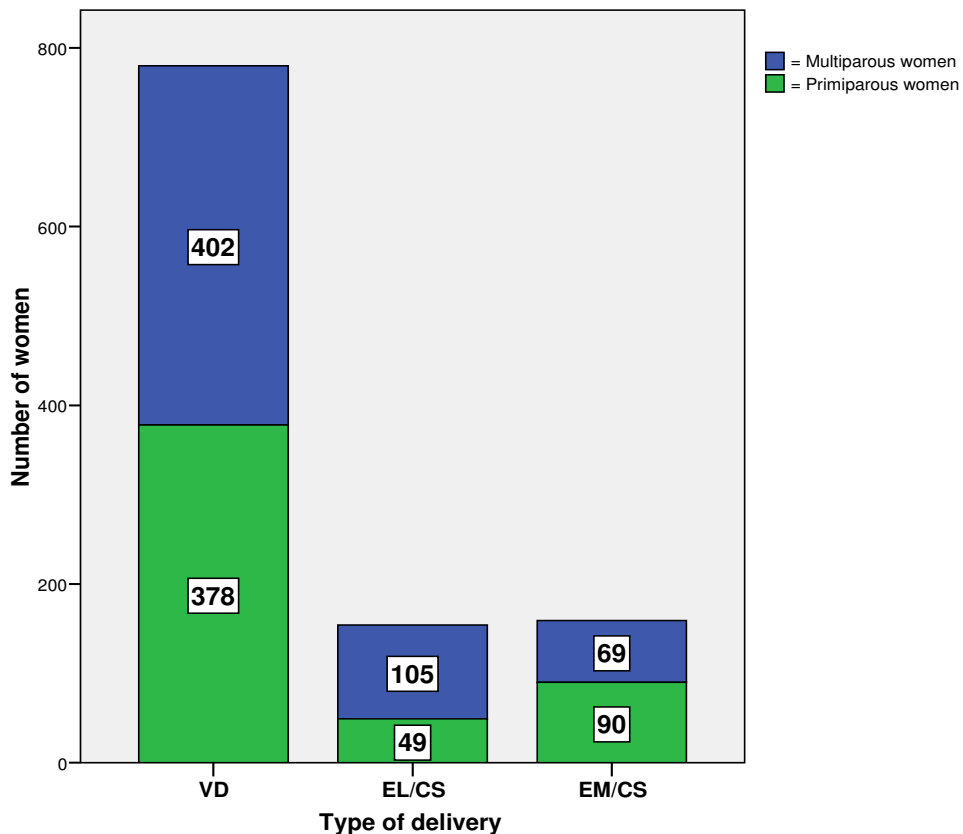


Figure 7: Reported number of women who had a vaginal delivery (VD) including instrumental / assisted deliveries (i.e. vacuum, forceps), elective caesarean section (EL/CS) or emergency caesarean section (EM/CS) birth at the Gold Coast Hospital during the data collection period for the 'Prevalence of breastfeeding study' (n=1093), grouped by the woman's parity.

Breastfeeding in an urban population

Table 3 gives an overview of the demographics of participants in our first study. The method of feeding on discharge from hospital was grouped by the participant's parity and type of delivery.

Table 3: Profile of the women from who gave birth at the Gold Coast Hospital, including their type of delivery, parity, and method of feeding when discharged from hospital during the period of data collection for the 'Prevalence of breastfeeding' study in 2008.

Method of feeding on discharge from hospital grouped by type of delivery and parity (N=1093).				
Delivery	Parity	Breastfeeding (%)	Artificial feeding & partially breastfeeding (%)	Total
Vaginal delivery	Primiparous	353 (93.4)	25 (6.6)	780 (100)
	Multiparous	343 (85.4)	59 (14.6)	
Elective caesarean section	Primiparous	43 (87.8)	6 (12.2)	154 (100)
	Multiparous	81 (77.1)	24 (22.9)	
Emergency caesarean section	Primiparous	79 (87.8)	11 (12.3)	159 (100)
	Multiparous	57 (82.6)	12 (17.4)	

Parity was a statistically significant predictor for breastfeeding exclusivity (Chi-Square=17.433, df = 2, $p<0.001$), as was type of delivery (Chi-Square=20.817, df = 4, $p<0.001$).

Findings from this study show that parity and type of delivery affected breastfeeding on discharge from hospital in this cohort of women. These findings show that multiparous women were more likely to be breastfeeding on discharge from hospital if they had elective caesarean sections, whereas primiparous women were most likely to be breastfeeding on discharge from hospital if they had vaginal deliveries.

Breastfeeding in an urban population

Table 4 compares the results of this study with the most recent feeding data from Queensland and the Gold Coast.

Table 4: Infant feeding methods reported by Queensland health in 2006, and the Gold Coast Hospital in 2006 (Perinatal Data Collection) & in 2008 (Data from Study 1).

Prevalence of exclusive breastfeeding at discharge from hospital:				
Data source	Exclusive breastfeeding (%)	Artificial feeding (%)	Partially breastfeeding (%)	Total
Queensland (QLD) Health Statistics Centre, 2006 ⁽¹²⁸⁾	44,855 (82.6)	6,875 (12.7)	2,534 (4.7)	54,296 (100)
Gold Coast Hospital (GCH): Perinatal Data Collection 2006 ^(125, 128)	2,262 (78.7)	487 (16.8)	131 (4.5)	2,875 (100)
Prevalence of breastfeeding from the Gold Coast hospital-2008 ⁽¹²⁹⁾	956 (87.5)	96 (8.8)	41 (3.8)	1093 (100)

Footnote: QLD = Queensland, GCH = Gold Coast Hospital

Conclusions

Limited data are available on local exclusive breastfeeding rates for the Gold Coast, Queensland. This study has reported several findings. The main finding from the data collected during the time of this study has shown that 87.5% of women exclusively breastfed on discharge from hospital. This represents an increase in the prevalence of breastfeeding compared to the Queensland Health Statistics for 2006 and the data from the perinatal data collection in 2006 for the GCH. Further to reporting the prevalence of breastfeeding in this population of women, findings from this study reported that, regardless of parity, women are most likely to exclusively breastfeed on discharge from hospital if they have vaginal deliveries, with 93.4% of primiparous

Breastfeeding in an urban population

rather than 85% of multiparous women, who have vaginal deliveries exclusively breastfeed on discharge from hospital. Comparing the results of this study with previous studies shows, that exclusive breastfeeding on discharge from hospital may have increased from 2006 to 2008 in the Gold Coast hospital.

An explanation for this finding could be that the 2006 data from QLD Health and the Gold Coast hospital are both from secondary data sources whereas our 2008 study on exclusive breastfeeding is primary data. Alternatively, the different data collection methods, interpretation of findings and data sources along with possible missing data in secondary sources, could account for the variation in the percentage of women who breastfeed.

These findings suggest a study to discover breastfeeding exclusivity and duration in an urban population. Chapter 4 will addresses this research question, reporting the results of a study conducted that observed the breastfeeding exclusivity and duration rates of the women who gave birth at the Gold Coast Hospital in 2008.

Chapter 4 Breastfeeding duration, exclusivity and knowledge of mastitis in an urban population

Introduction

Potential variables that are known to influence breastfeeding are explored in this study. Chapter 3 reported the demographic data and initiation rate of breastfeeding in the cohort of women who gave birth at GCH during January and April 2008. These findings included the method of feeding on discharge from hospital, women's parity, type of delivery and maternal age of the women. The main finding from this study reported that 87.5% of this cohort of women were discharged from hospital exclusively breastfeeding. This finding is an improvement on the 2006 QLD Health statistics of 82.6% of women discharged from hospital exclusively breastfeeding, but continues to be less than the recommendations made by the WHO, UNICEF and the NHMRC.

As previously discussed, Australia has a high initiation of breastfeeding but has little data on breastfeeding duration. In order to report the breastfeeding exclusivity and duration rates in an Australian population, the second study in this thesis observed a cohort of women for a period of six months. The aim of this study was to quantify breastfeeding exclusivity and duration in a population of women up to six months postpartum, explore the relationship between breastfeeding self-efficacy with exclusivity and duration of breastfeeding, and to conduct a pilot study investigating the knowledge of mastitis within this cohort of breastfeeding women.

Breastfeeding in an urban population

Methods

This longitudinal observational cohort study used both quantitative and qualitative methodologies in its design. The participants were recruited from the first study, the 'Prevalence of breastfeeding on the Gold Coast' study.

Subjects and Setting

The study cohort was comprised of 200 women who initiated breastfeeding while in hospital and continued breastfeeding when discharged. The women were purposefully selected as a sub-population from our previous breastfeeding study. The sample size was calculated to be a manageable number of participants to recruit and follow-up in the time allocated for this study, and provided adequate data to assess the research questions. A power calculation was not done for Study 2. This study was modified in order to meet the requirements of this Master's thesis and time restraints. This decision was made in consultation with relevant senior academic staff and supervisors to cap recruitment for this study at 200 participants.

Demographic data including age, parity, marital status, level of education and maternal occupation were collected and analysed.

Breastfeeding in an urban population

The following flow chart illustrates an outline of Study 2 methodology.

Methodology schema: Study 2 - Breastfeeding duration, exclusivity, and knowledge of mastitis in an urban population

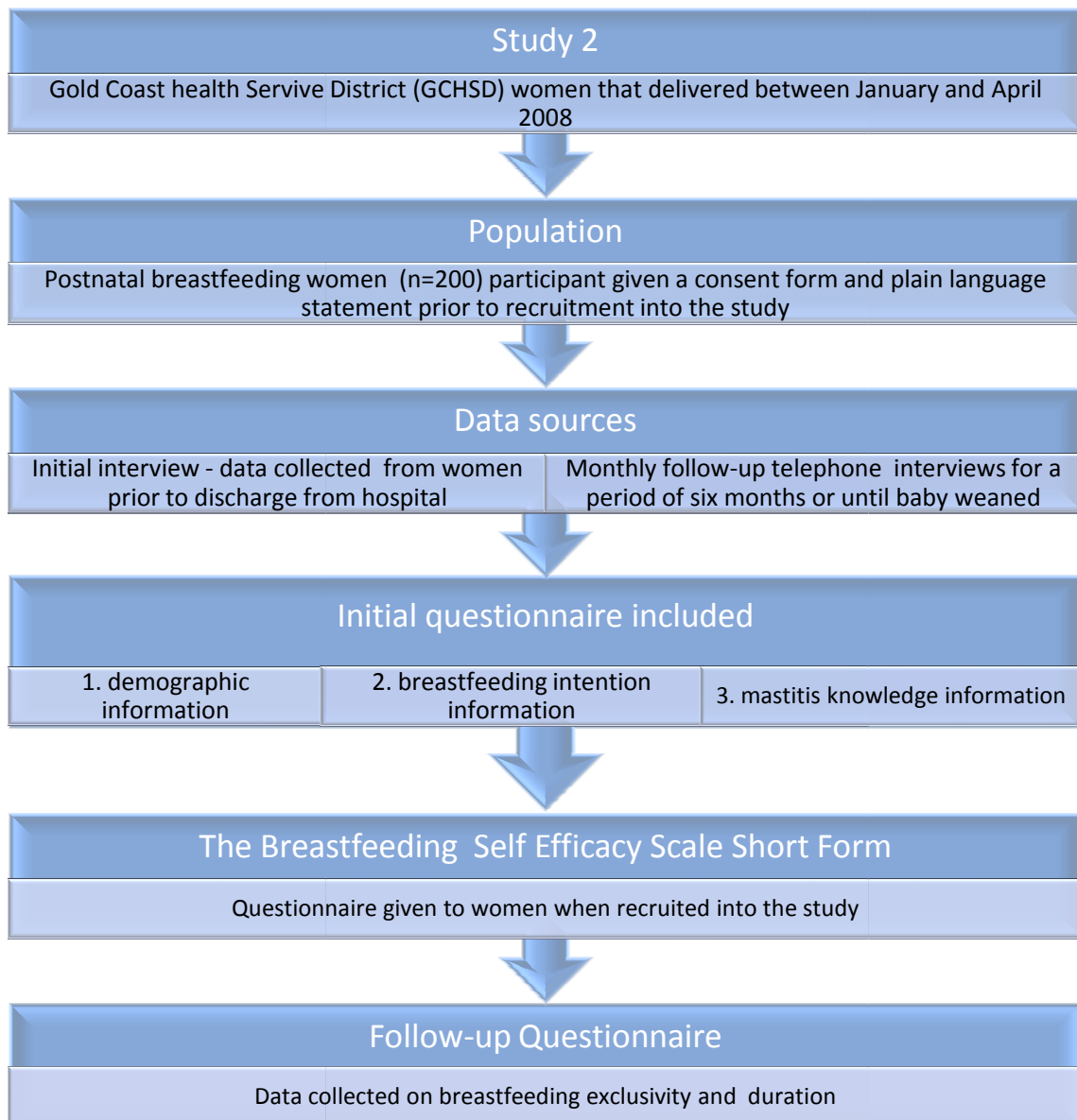


Figure 8: Flow chart illustrating an overview of the methodology used for Study 2 'Breastfeeding duration, exclusivity, and knowledge of mastitis in an urban population'.

Breastfeeding in an urban population

Inclusion and exclusion criteria

Breastfeeding women aged 18 years and over who gave birth at the Gold Coast hospital were eligible. Women, who did not have access to a telephone, did not speak English, or whose infants were in the special care nursery were excluded from the study.

Ethics approval

Ethics approval was obtained from both Bond University and Gold Coast Health Service District ethics committees. Each participant received a plain language statement and consent form prior to recruitment into the study. The plain language statement provided information on the study background, the questionnaires used, participant's confidentiality, risks and benefits of the study as well as emphasising that participation was voluntary.

Recruitment

Participants were recruited over a four-month period, commencing on the 8th January and ceasing on the 30th April 2008. Women were recruited on weekdays between the hours of 10 am and 2 pm so as not to interfere with the time that doctors and other health care professionals were consulting with them. Breastfeeding women who met the inclusion criteria were approached following consultation with the midwife in charge to ensure the appropriateness of contact. Each woman was given a brief outline of the project, asked to read a plain language statement and sign a consent form. Recruitment of participants, as well as data collection, was conducted by a qualified

Breastfeeding in an urban population

lactation consultant who was also an experienced researcher, with skills in interviewing and data collection.

Data collection

After giving consent, the participants completed an initial questionnaire as well as the 'Breastfeeding Self Efficacy Scale' Short Form (BSES-SF). Participants subsequently completed a monthly telephone interview for six months or until they ceased breastfeeding. The participants had contact with the same research officer for the duration of the study in order to maintain the integrity of collected data.

The initial interview was conducted prior to discharge from hospital using the following tools:

1. Initial questionnaire which included three sections:
 - a. Demographic information
 - b. Knowledge of mastitis questions
 - c. Breastfeeding intention
2. Breastfeeding self efficacy scale – short form

Longitudinal data on breastfeeding exclusivity and duration were collected via telephone follow-up interviews.

Breastfeeding in an urban population

The initial questionnaire

The interviews were conducted at the patient's hospital bed to ensure the least amount of disturbance and inconvenience to both the mother and staff members. Interviews took approximately 15-20 minutes to conduct, allowing time for the mother to attend to her infant's needs as appropriate.

During the face-to-face interviews, the research officer collected data on personal demographics, breastfeeding practice, breastfeeding intention, and knowledge of mastitis. The design of the questions required short answers or YES/NO response when appropriate. The initial questionnaire consisted of 21 questions (see Appendix 1), including the following data:

Demographics: Maternal Age, Marital status, level of education and occupation

Maternal history: Infant's date of birth and parity

Level of education was divided into four categories: Completed year 10 or less; Completed up to year 12; Trade diploma TAFE; Bachelor degree or higher. Occupation was divided into six categories: Nil paid employment; Self-employed and business owners; Tradesperson and labourers; Clerical and service workers; Managers and administrators; and Professionals and associate professionals.

Knowledge of mastitis:

This study provided an opportunity to collect qualitative pilot data from a cohort of breastfeeding women on their knowledge of mastitis. As previously outlined, how

Breastfeeding in an urban population

mastitis is defined varies throughout the literature, with a difference in origins of the term used by laypersons to professionals.

Including self-diagnosis and treatment to clinical diagnosis with a health care professional.

The following three questions were asked at interview:

- What is mastitis?
- How do you treat mastitis?
- Where did you find this information?

If the women did not know the answer, the next question was asked. The response frequency for each question was calculated and grouped. This information provided findings that were compared to the clinical definition of mastitis and accepted clinical treatments.

Breastfeeding intention:

Participants were asked about their feeding intention within the categories listed below. Exclusive breastfeeding was defined as 'fully breastfeeding without the introduction of formula or solids'.

- Exclusive breastfeeding;
- Feeding expressed breast milk;
- Formula feeding; and

Breastfeeding in an urban population

- Combination of breastfeeding and formula feeding

The women were also asked if they intended to demand feed or schedule feed their infants.

The Breastfeeding Self Efficacy Scale Short Form (BSES-SF)

Research has identified the need to improve breastfeeding duration and exclusivity rates. Health professionals who are able to assess woman at risk of weaning prematurely may identify predisposing factors amenable to intervention. One possible modifiable variable is breast-feeding confidence. The Breastfeeding Self-Efficacy Scale-Short Form (BSES-SF) is a 14-item measure designed to assess a mother's confidence in her ability to breastfeed her baby. Each item is scaled in the form of optimistic statements, with answers ranging between 1 (not at all confident) and 5 (very confident) on a Likert scale. Item scores are summed to produce a final BSES-SF score, with a possible range between 14 and 70. The higher scores signify a greater breastfeeding self-efficacy. The BSES-SF tool was developed to assist health professionals to assess breastfeeding confidence a known modifiable variable that influences breastfeeding success. This tool assists health professionals to identify woman who are high-risk of stopping breastfeeding before the recommended 6 months post partum.

The BSES is a reliable measure of new mothers' confidence in breastfeeding, with a Cronbach's reliability of 0.95.⁽¹³⁰⁾ This instrument has been used in several studies and has proved to be valid and reliable.⁽¹³⁰⁾

Breastfeeding in an urban population

In 2002 a reliability analysis was conducted in a longitudinal study by the designer of this tool, Dr Cindy-Lee Dennis to validate the BSES-SF as a predictor of breastfeeding confidence and behaviour.⁽⁶⁷⁾ The construct validity of this tool was assessed using principal components factor analysis, comparison of contrasted groups, and correlations with measures of similar constructs.⁽⁶⁷⁾ Participants for this study included a population-based sample of 491 breastfeeding women in British Columbia.⁽⁶⁷⁾ Predictive validity of this tool was demonstrated and reported in this study through significant mean differences between breastfeeding and bottle-feeding mothers at 4 ($p < .001$) and 8 ($p < .001$) weeks postpartum.

Permission to print and use the scale was obtained from the copyright holder, Dr Cindy-Lee Dennis at the design phase of this thesis. Data pertaining to breastfeeding confidence were collected from participants when recruited into Study 2 using the Breastfeeding Self efficacy Scale-Short Form (BSES-SF questionnaire)^(67, 131) (see Appendix 2).

Breastfeeding in an urban population

Telephone follow-up Interview

Monthly telephone interviews were conducted for a six month period or until the participants weaned their infant. Each participant was asked whether they were still fully breastfeeding, or had commenced formula or solids. Questions used YES/ NO responses. The date the infant weaned and started formula/ solid food was also collected. These data enabled the calculation of the duration of exclusive or any breastfeeding. Women who were still breastfeeding at six months were deemed to have breastfed until that date although they may have breastfed for a much longer time. The follow-up telephone interviews were short, so as not to inconvenience the participants.

Lost to follow-up

16 participants were lost to follow-up due to the following categories: 13 women were unable to be contacted due to telephone challenges, including change to telephone number, disconnection or contact details. One woman requested that she no longer be contacted with regards to the project, and withdrew consent due to her busy schedule. One woman moved overseas, and another withdrew from the study at her husband's request.

Breastfeeding in an urban population

Statistical analysis

Quantitative data

Quantitative data was analysed using SPSS version 17.0 for windows.⁽¹²⁷⁾

To substantiate if the participants of the second study that reported exclusivity and duration of breastfeeding were a representative subgroup of study 1 on the prevalence of breastfeeding, age and parity of the two groups were compared using a t-test.

A descriptive analysis was undertaken of the demographic variables collected in the exclusivity and duration of breastfeeding study. The participants' ages were described with a mean and standard deviation. Marital status, parity, level of education and occupation were described using percentages, and t-tests were used to report differences between groups. Correlations were used to investigate relationships between continuous variables, while a Chi-Squared test was used to test any relationships between discrete variables. A Kaplan-Meier survival analysis (KMSA) was used to compare parity for both breastfeeding exclusivity and duration.

Questions that relate to breastfeeding intention were analysed using proportions and percentages. A correlation between breastfeeding exclusivity, duration, education and occupation was used to report findings between these variables.

Breastfeeding in an urban population

Data collected on the BSES-SF were reported using range and mean values. Correlations were used to investigate the relationship of BSES-SF and breastfeeding exclusivity and duration.

Qualitative data

To report findings from qualitative data collected, the answers were collated and a thematic analysis undertaken. While most women gave more than one response to each question, the primary answer was used to best describe each response. If a woman gave a multiple description response, it was grouped to best describe the answer. Data collected were numerically coded and grouped into common themes.

Results

Representative sub-sample

Data collected on age and parity were used to confirm the sample used was a representative subgroup of the breastfeeding prevalence study population. Data on marital status were not available from the breastfeeding prevalence study, therefore a comparison for this variable between the two studies was not possible.

The age range differed between the two groups, with the minimum age in the breastfeeding prevalence study being less than in the exclusivity and duration of breastfeeding study (15 vs. 19 years). This was due to ethical guidelines in the exclusivity and duration study stipulating that participants were at least 18 years old. The maximum age in both groups was 48 years. The mean age was 28.89 ± 5.79 years in the breastfeeding prevalence study, and was 28.93 ± 5.63 years in the exclusivity

Breastfeeding in an urban population

and duration of breastfeeding study. An independent sample t-test indicated there was no statistically significant difference between the groups for age, $t(198) = -1.427$, $p=0.08$.

A comparison for parity between the two studies was conducted to ensure that the Study 2 population was representative of Study 1 parity, $t(199) = 1.470$, $p= 0.001$. This is illustrated in the table below. There were no significant differences in the numbers of primiparous and multiparous women between Study 1, the Prevalence of breastfeeding and Study 2, Exclusivity/duration of breastfeeding studies.

Table 5: Comparison of the women's parity between our two studies 'Prevalence of breastfeeding study' and 'Exclusivity and duration of breastfeeding study' in 2008.

Study	Primiparous women	Multiparous women	N	χ^2	df	P value
Prevalence of breastfeeding	517 (47)	576 (53)	1093	2.90	1	0.06
Exclusivity and duration of breastfeeding	106 (53)	94 (47)	200			

Breastfeeding in an urban population

Demographics of exclusivity and duration of breastfeeding study participants

Of the 200 breastfeeding women in this study, 91.5% were either married or in a de-facto relationship. A frequency distribution of the women that had between 1 and 7 live infants has been illustrated in Figure 9. Of the 200 women, 106 (53%) were primiparous.

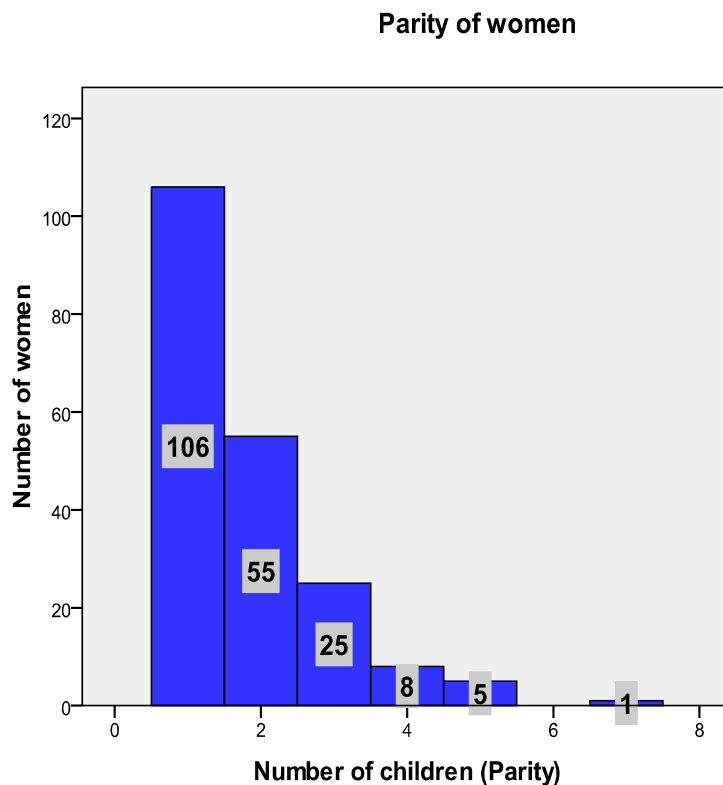


Figure 9: Frequency distribution of the number of children (parity) of the women from the 'Breastfeeding exclusivity and duration study' (n=200).

Demographic data collected on each participant's occupation and level of education were collected and categorised. The scale used to measure this data was a modified version of the categories used by the Australian Bureau of Statistics (ABS) 2006

Breastfeeding in an urban population

Australian and New Zealand Standard Classification of Occupations (ANZSCO).⁽¹³²⁾ The education scale is designed to rank levels of education obtained by the participant, while occupation is grouped by categorical types. These data provided a descriptive profile of this cohort of participants. The findings are described in Table 6.

Table 6: Frequency of categorical variables for education and occupation as reported on the women in Study 2.

Education categories	Study 2 participants (%)
Completed year 10 or less	30 (15)
Completed up to year 12	67 (33.5)
Trade diploma TAFE	50 (25)
Bachelor degree or higher	53 (26.5)
Total	200 (100)
Occupation	
Nil paid employment	2 (1)
Self-employed & business owners	49 (24.5)
Tradesperson & labourers	13 (6.5)
Clerical & service workers	71 (35.5)
Managers & administrators	22 (11)
Professionals & associate professionals	43 (21.5)
Total	200 (100)

When asked their breastfeeding intentions, the majority of women reported that they intended to fully (exclusively) breastfeed. Similarly, the majority of women intended to demand rather than schedule feed on discharge from hospital, as illustrated in Table 7.

Breastfeeding in an urban population

Table 7: Breastfeeding intention data, collected from the women in Study 2 – ‘Breastfeeding exclusivity, duration, and knowledge of mastitis study in an urban population’.

Description (Questions as asked in survey)	Parity	
	Primiparous (%)	Multiparous (%)
I intend to fully (exclusively) breastfeeding this infant	105 (99)	93 (99)
I intend to both breastfeed and formula feed this infant	1 (1)	1 (1)
Total	106 (100)	94 (100)
Description (Question as asked in survey)		
I intend to demand feed rather than schedule feed	77 (73)	76 (81)
Total	106 (100)	94 (100)

On discharge from the Gold Coast hospital, all of the participants interviewed were either exclusively (99%) or partially (1%) breastfeeding. Data were collected from participants while in hospital and at the follow-up interviews, that enabled both exclusivity and total duration of any breastfeeding to be calculated.

Length of exclusive breastfeeding data were collected from 184 of the 200 women and reported a mean of 95.27 ± 73.40 days of exclusive breastfeeding. Data collected from 197 of the 200 women for a period of six months reported a mean of 125.36 ± 70.47 days total breastfeeding. There was a marked decrease of 18% in breastfeeding

Breastfeeding in an urban population

duration and 27% of exclusivity at 2 months. At the end of the trial, 59% of women were still breastfeeding, with 35% doing so exclusively.

Breastfeeding in an urban population

Inferential statistics

Using a Pearson's correlation coefficient, there was a statistically significant positive correlation between an increase in maternal age and an increase in the number of children (parity), $r(200) = 0.31$, $p < 0.001$. There was also a statistically significant positive correlation between an increase in maternal age and an increase in breastfeeding exclusivity $r(184) = 0.20$, $p < 0.007$, but not duration, $r(197) = 0.12$, $p > 0.10$. In addition, there was a positive relationship between an increase in length of exclusive breastfeeding and an increase in parity $r(184) = 0.72$, $p < 0.001$, and an increase in total duration of breastfeeding within the parameters of this study, $r(184) = 0.72$, $p < 0.001$. A Pearson's correlation coefficient also showed that there was a statistically significant correlation between women who were in a relationship and an increase in breastfeeding exclusivity, $r(184) = 0.73$ $p = 0.03$, and duration, $r(197) = 0.02$.

A Chi-Squared analysis, showed a significant relationship between the number of children (parity) and the women's increased level of education, $\chi^2(3, N = 200) = 13.96$, $p < 0.003$ and occupation category, $\chi^2(5, N = 200) = 98.44$, $p < 0.001$.

A strong positive correlation was reported between exclusivity and total duration of breastfeeding, $r(184) = 0.72$, $p < 0.001$.

A Kaplan Meier survival curve has been used to describe survival characteristics and to plot the clinical outcomes for breastfeeding exclusivity and duration in this population

Breastfeeding in an urban population

of breastfeeding women for the period of this study (6 months). Each participant's breastfeeding behavior (breastfeeding exclusivity and duration) was followed from hospital discharge until they ceased exclusive breastfeeding or until the end of this study. The outcome is unknown of those participants who have withdrawn from the study. For all these cases the time of follow-up is recorded.

The six month breastfeeding exclusivity and duration rates grouped by parity for our second study, *Exclusivity and duration of breastfeeding in an urban population*, has been reported in the Kaplan Meier survival curve. See figure 10 and 11 below. Figure 10 reports the difference in total duration of breastfeeding between the groups, over a period of six months. Figure 11 reports the difference in exclusive breastfeeding rates grouped by parity, over a period of six months. Both graphs illustrate that multiparous women in the study had a greater exclusivity and duration of breastfeeding.

Breastfeeding in an urban population

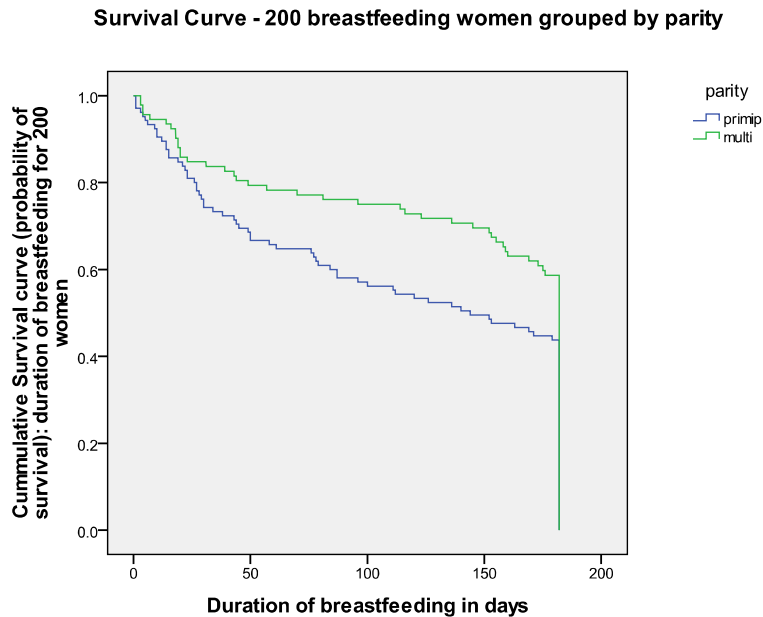


Figure 10: Survival curve of breastfeeding duration grouped by parity for a six month period of the women from Study 2 'Breastfeeding exclusivity, duration and knowledge of mastitis in an urban population' (n=200).

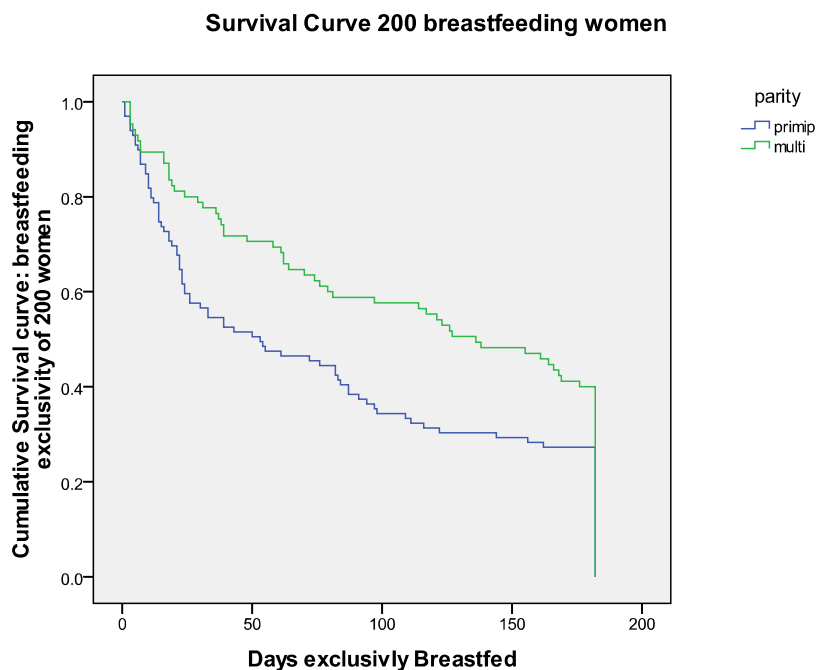


Figure 11: Survival curve for breastfeeding exclusivity grouped by parity for a six month period of the women from Study 2 'Breastfeeding exclusivity, duration and knowledge of mastitis in an urban population' (n=200).

Breastfeeding in an urban population

Breastfeeding duration was reported for both the primiparous (mean 113 ± 73 days) and multiparous women (mean 139 ± 66 days). The minimum duration of any breastfeeding within this cohort of women was less than 1 week, and the maximum was 26 weeks (breastfeeding may have continued past the study completion). An independent sample t-test showed that the average duration of breastfeeding was significantly greater for multiparous than for primiparous women ($t(195) = 2.58, p < 0.01$).

Breastfeeding exclusivity was also reported for primiparous (mean 80 ± 72 days) and multiparous women (mean 113 ± 71 days). The average number of days of exclusive breastfeeding was greater for multiparous than primiparous women, $t(182) = 3.14, p < 0.002$).

Breastfeeding at one month

While the participants in this study were purposefully recruited as breastfeeding women, 88% of women were reported to be exclusively breastfeeding at one month, with a further 8% non-exclusively breastfeeding. Breastfeeding at one month was compared with findings from Study 2 on exclusivity and duration study in 2008 and other Australian credible data sources. The data reported from other sources is the percentage of women who were giving their infants some breast milk, albeit not necessarily exclusive breastfeeding, at one month. While it is understood that these data were collected by different methodologies, it is the best available comparative information.

Breastfeeding in an urban population

The 2008 Gold Coast Hospital (GCH) study 2, data reported the highest rates of feeding at one month. While the 2004 Australian Longitudinal Study (ALS) reported the lowest levels of both full and any breastfeeding (with only 71% of infants fully breastfed at one month); however, the Australian Longitudinal Study (ALS) rate increased to 83% in 2008. This is in line with the 2006 National Health and Medical research Council (NHMRC) and 2008 Queensland (QLD) Health data breastfeeding rates.⁽¹³³⁾

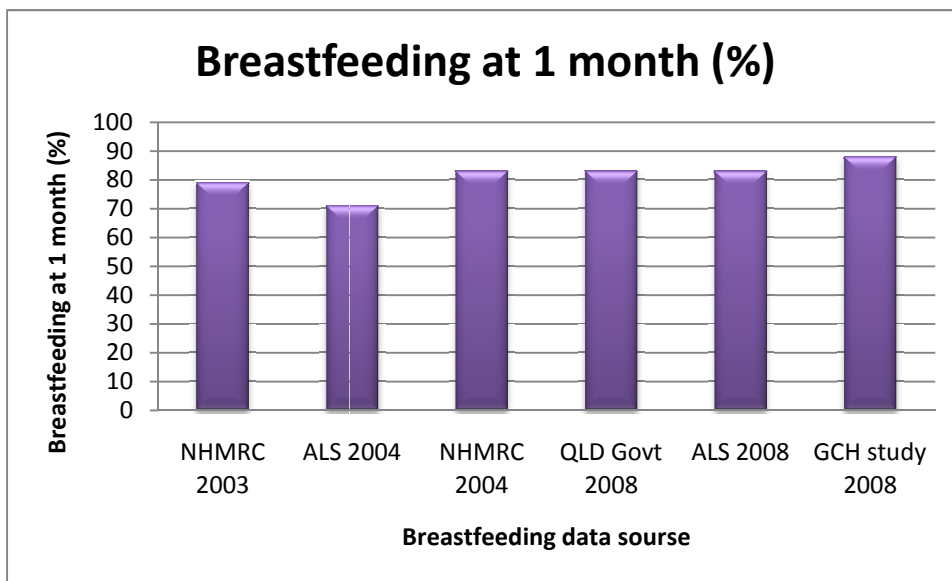


Figure 12: Breastfeeding trends at one month from several available sources (see Footnote below) This figure illustrates the comparison of breastfeeding rates at 1 month as reported from available sources including the women from Study 2 'Breastfeeding exclusivity, duration and knowledge of mastitis study in an urban population' (n=200).

Footnote: Australian longitudinal Study 2004 & 2008 (ALS). National Health and Medical Research Council (NHMRC). Queensland Government Perinatal data (QLD Govt). Gold Coast Hospital – Study 2 (GCH study).

Breastfeeding in an urban population

Education and occupation

There was a strong relationship between level of education and the scale of occupation, ($r = 0.51$ (200), $p < 0.001$). A higher level of maternal education had a positive correlation with both an increase in breastfeeding exclusivity, ($r = 0.24$ (184), $p < 0.001$) and increase in the duration of breastfeeding ($r = 0.23$ (197), $p < 0.001$). There was a positive correlation between maternal occupation and an increase in breastfeeding duration, ($r = 0.51$ (197), $p > 0.047$).

Breastfeeding in an urban population

The 'Breastfeeding Self Efficacy Scale' short form (BESE-SF)

The 200 (100%) study participants recruited completed the BSEF-SF at recruitment.

Scores ranged from 24-70 with a positively skewed distribution and a mean of $54.25 \pm$

9.76. Figure 13 illustrates the participants' scores at the first interview.

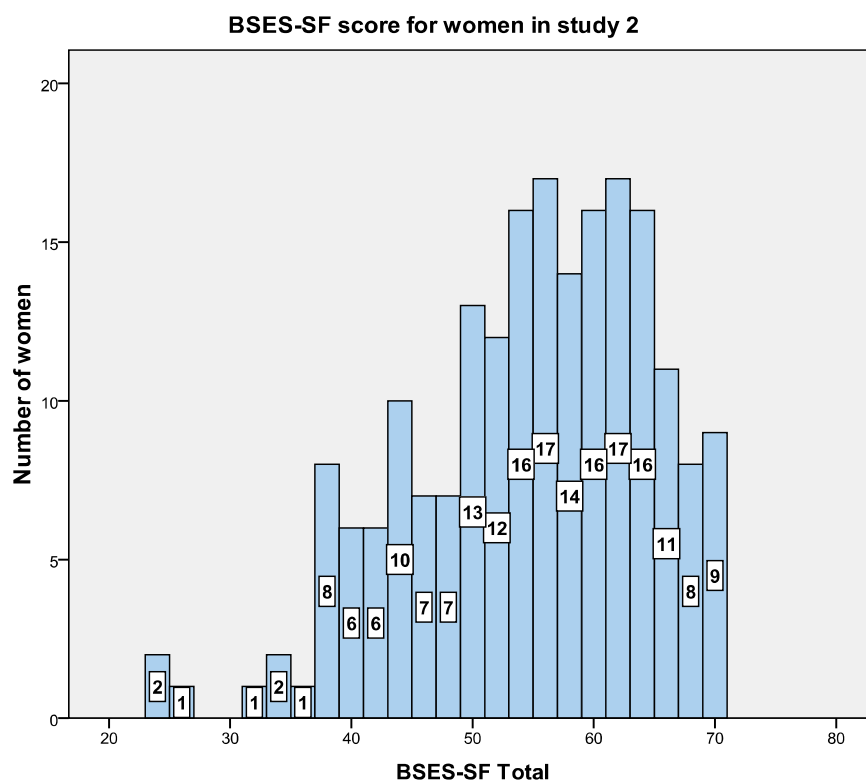


Figure 13: Breastfeeding Self Efficacy Scale – short form (BSES-SF) score distribution. Data collected from the participants during the initial interview when recruited into Study 2 - 'Breastfeeding exclusivity, duration and knowledge of mastitis study in an urban population' (n=200).

Breastfeeding in an urban population

Using a Pearson's correlation coefficient there was a statistically significant positive relationship between the BSES-SF score and exclusivity ($r(184) = 0.36, p < 0.001$).

Relationship between the Breastfeeding Self Efficacy Scale - short form score and breastfeeding exclusivity

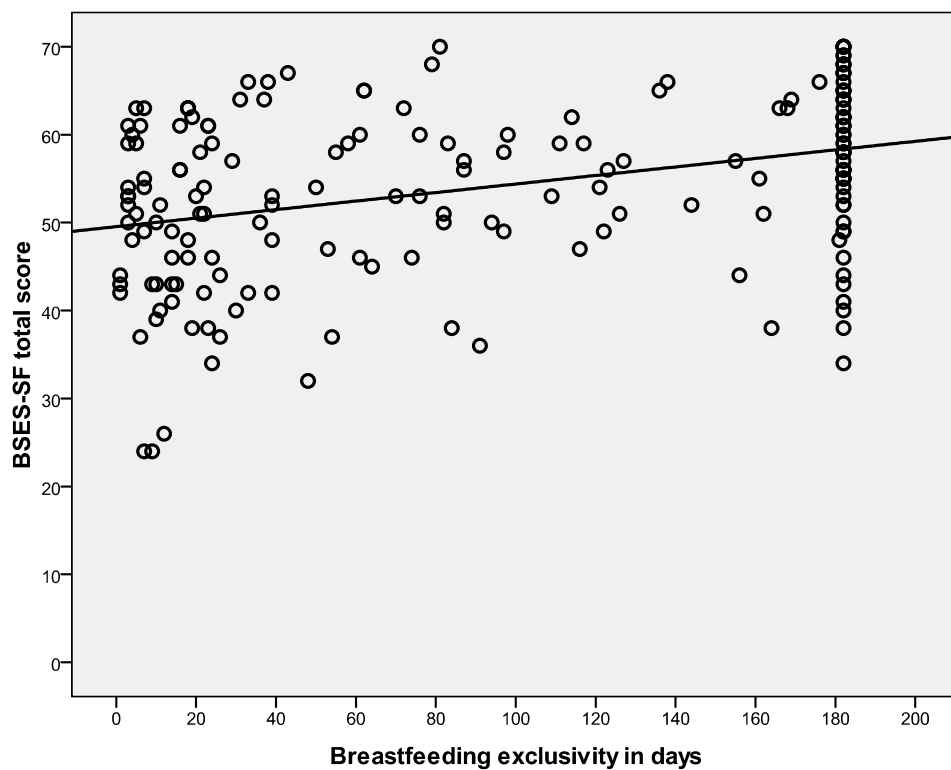


Figure 14: Scatter pot – illustrating the relationship between the Breastfeeding Self Efficacy Scale - short form (BSES-SF) score and the number of days that women exclusively breastfeed (maximum of 182 days of exclusive breastfeeding reported) from Study 2 participants (n=200).

Breastfeeding in an urban population

Using a Pearson's correlation coefficient there was a statistically significant positive relationship between the BSES-SF score and duration ($r(197) = 0.38, p < 0.001$).

Relationship between the Breastfeeding Self Efficacy Scale - short form score and breastfeeding duration

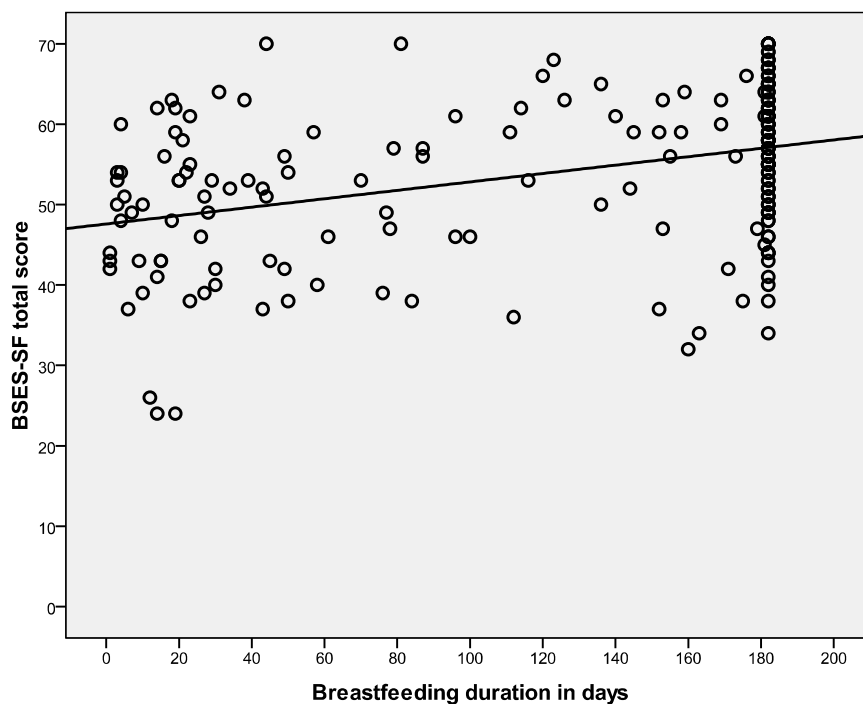


Figure 15: Scatter Plot – illustrates the relationship between the Breastfeeding Self Efficacy Scale - short form (BSES-SF) score and the total duration of breastfeeding reported (maximum of 182 days duration of breastfeeding reported) from Study 2 participants (n=200).

Breastfeeding in an urban population

Women's knowledge of mastitis

The final section of this chapter reports pilot data collected on the women's level of knowledge with regard to mastitis. As highlighted in Chapter 1, one of the aims of this study was to collect pilot data on this population of breastfeeding women pertaining to their understanding of mastitis. The collected data was compared with the clinical definition of mastitis to identify if it was consistent.

The women were asked three questions regarding their knowledge of mastitis. All three questions had a degree of overlap with participants' responses. Participants' responses were categorized and the frequencies of responses were calculated and reported. The first question asked about the women's knowledge of mastitis. The second question asked about the women's knowledge of how to treat mastitis, and the third question asked the women where they had received this information.

The pilot data collected resulted in nine main categories of responses for Question 1: 'What is mastitis'. Of the 200 women asked this question, only 152 (76%) offered a response. When more than one response was given overlaps were categorised into the appropriate groups. The women related mastitis to breast changes including infection, inflammation, engorgement, blocked ducts, lumps, and pain with or without flu-like symptoms. The most frequent response was in relation to infection with pain and breast blockages. The three most common responses all represent the signs and symptoms of mastitis. Therefore, the majority of women have some understanding of mastitis, but the trend was to identify mastitis with varying degrees of the disease. None of the interviewed women gave a complete description of what mastitis is and

Breastfeeding in an urban population

how it can affect lactation. The following figures report the frequency of responses for each category of answer per question.

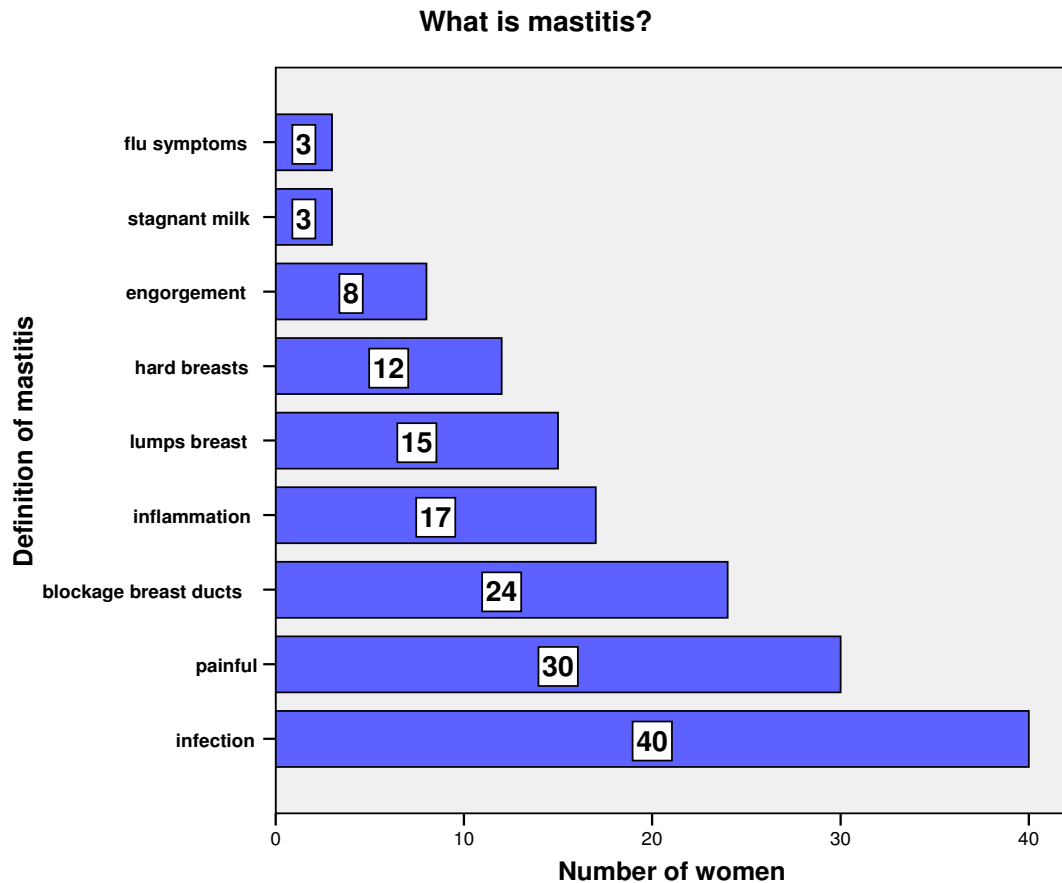


Figure 16: Frequency distribution of responses for question (1) reporting the women's knowledge of mastitis: What is mastitis?

Following the first question, the women were asked if they knew how to treat mastitis. Of the 200 women, only 111 (55.5%) attempted to answer this question. Of the six categories found, the most frequent indicated that the women would consult their GP for antibiotics and analgesics. The second most common category indicated that they would keep breastfeeding and identified the importance of draining the affected

Breastfeeding in an urban population

breast, possibly by milk expression. Figure 17 illustrates the women's responses to treating mastitis.

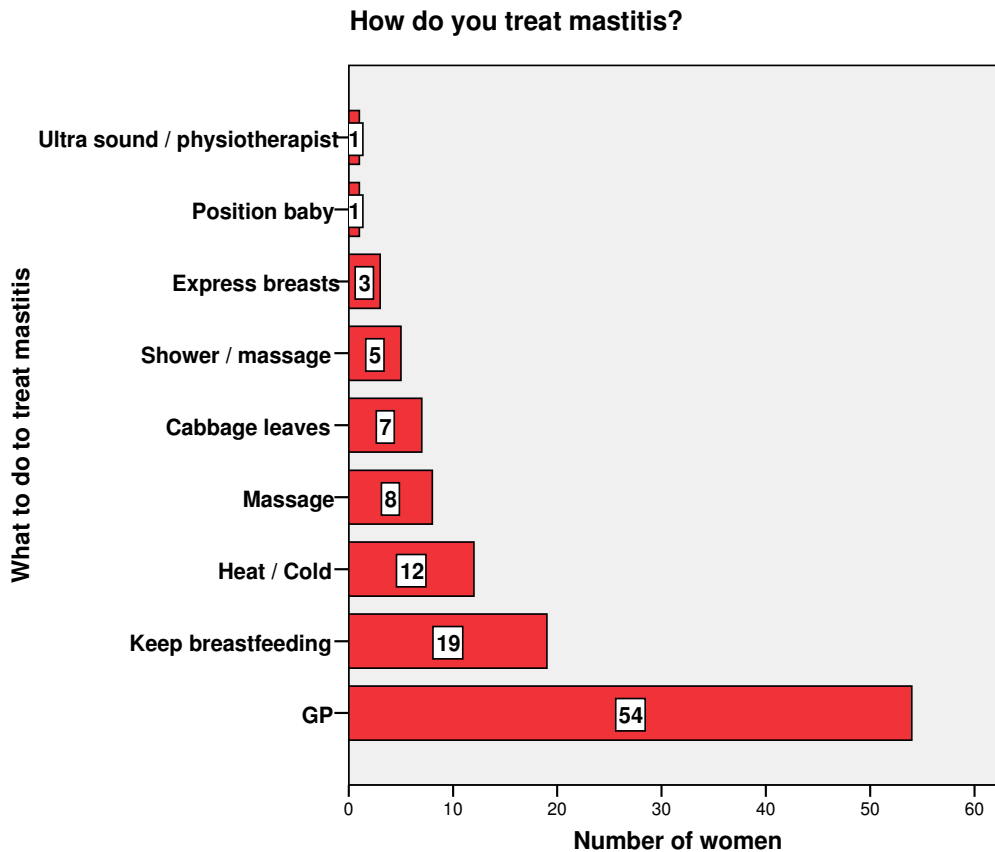


Figure 17: Frequency distribution of responses for question (2) reporting the women's knowledge of mastitis: How do you treat mastitis?

Question 3, 'Where did you find this information', was designed to identify where the women sourced the information with regards to mastitis treatment. Of the 200 women interviewed, 125 (62.5%) answered this question. Eleven main categories were identified in the data collected. The most popular source for obtaining information was from mothers, friends, and peers. The second highest source of information was from the library, books, magazines, and the media. The GP or

Breastfeeding in an urban population

obstetrician responses were closely followed by intrinsic knowledge. Intrinsic knowledge was knowledge that they had taken for granted (and assumed everyone knew). The categories that define how the women found this information are illustrated in figure 18.

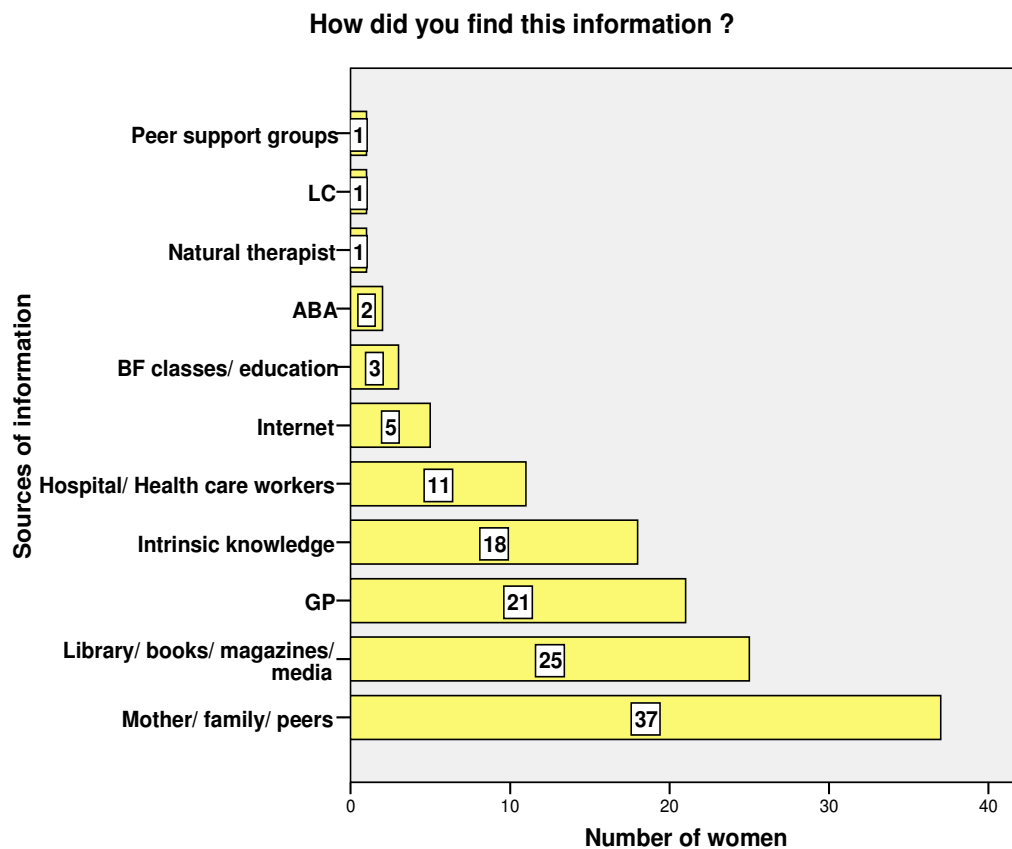


Figure 18: Frequency distribution of responses for question (3) reporting the women's knowledge of mastitis: How did you find this information?

Breastfeeding in an urban population

Conclusions

In summary, the majority of the women in the exclusivity and duration of breastfeeding study were primiparous, with a mean age of 28.9 years. Most women were either married or in a defacto relationship (rather than single), and the majority worked in either clerical/sales or service occupations. The highest level of education of the majority of women in this cohort was completion of Year 10 or 12.

All participants in this study intended to breastfeed to some degree. Of the 200 women recruited, data was collected on 184 of these participants concerning exclusivity of breastfeeding and 197 for duration of breastfeeding. There was a marked decrease in both exclusivity and duration of breastfeeding at the one-month mark, and only 59% of women breastfed until the recommended six months of age. Multiparous women and older women were more inclined to exclusively breastfeed for a longer duration.

An increase in the women's level of education had a positive impact on exclusivity and duration of breastfeeding, whereas occupation did not; however, an increase in breastfeeding self efficacy score (BSES-SF) was seen to be a key factor in breastfeeding success, both with regards to exclusivity and duration.

Finally, while most women had a degree of understanding and knowledge of what mastitis is, the participants were generally unable to accurately describe the condition or explain appropriate management. These findings highlighted firstly the need for education about lactation complications to new mothers and the general community and, secondly, the need for investigation into preventative interventions for mastitis

Breastfeeding in an urban population

during this period. As a result, a Cochrane Systematic review of the interventions to prevent mastitis following childbirth was conducted (see Chapter 5).

Chapter 5

Study 3 Cochrane systematic reviews - 'Intervention for the prevention of mastitis after childbirth'

(Note: Cochrane Systematic Review published in the Cochrane Library 2010, issue 8. See full Cochrane Systematic Review as Appendix 3)

Background

Despite the health benefits of breastfeeding, initiation and duration rates continue to fall short of international guidelines. Many factors influence a woman's decision to wean. The main reason cited for weaning is associated with lactation complications, such as mastitis.

Methods

Objectives

To assess the effects of preventive strategies for mastitis and the subsequent effect on breastfeeding duration.

Search methods

The Cochrane Pregnancy and Childbirth Group's Trials Register (June 2008), CENTRAL (*The Cochrane Library* 2008, Issue 3), MEDLINE (1950 to July 2008), EMBASE (1974 to June 2008), CINAHL (1981 to July 2008), MIDIRS (1971 to July 2008), IPA (1970 to July 2008), AMED (1985 to July 2008) and LILACS (1982 to July 2008).

Breastfeeding in an urban population

Selection criteria

We included randomised controlled trials of interventions for preventing mastitis in postpartum breastfeeding women.

Data collection and analysis

We independently identified relevant studies and assessed the trial quality. Trial authors were contacted for missing data and information as appropriate.

Results

We included five trials (involving 960 women). No significant differences in the incidence of mastitis were seen between use of antibiotics and no antibiotics in three trials of 471 women (risk ratio (RR) 0.43; 95% confidence interval (CI) 0.11 to 1.61), or in one trial of 99 women comparing two doses (RR 0.38; 95% CI 0.02 to 9.18). There were also no major differences seen for mastitis in three trials of specialist breastfeeding education with usual care (one trial); anti-secretory factor cereal (one trial); and mupirocin, fusidic acid ointment or breastfeeding advice (one trial).

Generally, no differences were seen in any of the trials for breastfeeding initiation, duration, or symptoms of mastitis.

Authors' conclusions

There was insufficient evidence to show effectiveness of any of the interventions (including breastfeeding education, pharmacological treatments, and alternative therapies) regarding the occurrence of mastitis or breastfeeding exclusivity and

Breastfeeding in an urban population

duration. While studies reported the incidence of mastitis, they all used different interventions. Caution needs to be applied when considering the findings of this review as the conclusion is based on studies, which often had small sample sizes. This highlights a need for further adequately powered research into the effectiveness of interventions for the prevention of mastitis.

Chapter 6 Discussion

Introduction

As outlined in Chapter 2, this thesis consisted of three studies. The aims of these were:

- to collect quantitative data to report the prevalence of breastfeeding amongst women who birth at the Gold Coast Hospital and to identify if they are consistent with national breastfeeding initiation rates;
- to quantify the breastfeeding exclusivity and duration rates in this population of women, comparing them with national rates; and
- to conduct a Cochrane Systematic Review to investigate issues around mastitis, focussing on interventions to reduce the incidence of mastitis and their effectiveness in the postnatal breastfeeding period.

The second study also provided an opportunity to collect pilot data on the participants' understanding of mastitis, to identify if it was consistent with the clinical definition.

Summary

As previously discussed, in 2003 Queensland Health established breastfeeding targets to be achievement by 2008. These guidelines outlined that 60% of infants be exclusively breastfed in the first three months, and for 50% of infants to be exclusively breastfed in the first 6 months.⁽¹³⁴⁾ These targets fall short of the guidelines set out by WHO and UNICEF but are a step in the direction of improving current trends. Study 1 of this thesis, the prevalence of breastfeeding study, showed that the breastfeeding

Breastfeeding in an urban population

exclusivity rates of women on discharge from hospital are similar to both state and national breastfeeding rates previously reported. As with data reported on the Infant Nutrition Project 2006–2007,⁽¹³⁴⁾ which shows that 38% of infants in the cohort were exclusively breastfed at two months of age, and only 9.5% at five months of age, these were substantially lower than the targets set by Queensland Health for 2008.⁽¹³⁴⁾ Findings from the first and second study in this body of work reported the prevalence, exclusivity and duration of breastfeeding in a cohort of women who gave birth at the Gold Coast Health Service. Both these studies support the notion that Australia continues to have high breastfeeding initiation rates but sub-optimal exclusivity and duration rates. The sub-group study was a demographically representative sample from the initial breastfeeding prevalence study, and the factors identified to be predictors of breastfeeding exclusivity and duration were similar to those identified in previous work (e.g. maternal age, parity, marital status, education and occupation).

The sub-group study also highlighted that women's understanding of mastitis is limited, and does not align with the clinical definition. Moreover, women with mastitis initially self-manage their condition and only seek treatment from their general practitioner as symptoms worsen. Finally, our systematic review of the interventions to prevent mastitis (that have been trialled previously) showed that insufficient evidence exists to suggest that any of these interventions is beneficial.

Chapter 3, 'Prevalence of breastfeeding at the Gold Coast Hospital' (study 1), reported that 88% of women exclusively breastfed upon discharge (a further 4% were partially breast/ formula feeding). The combined prevalence of breastfeeding initiation in this

Breastfeeding in an urban population

population of 92% is clinically significant in comparison to other data reported. These findings were similar to the 2009 Australian Longitudinal Study of 91%, followed by the 2008 QLD Health perinatal data collection statistics of 83%, all of which approach or exceed the recommended target of 90% by NHMRC.⁽¹³⁵⁻¹³⁷⁾ Despite the fact that the QLD Health perinatal data (2008) reported 83% of infants were exclusively breastfed, and a further 5% were given both formula and breast milk on discharge from hospital⁽¹³⁸⁾, the Queensland Government Chief Health Officer's report stated that breastfeeding was not sustained long enough in Queensland.

The difference in breastfeeding rates between this study and the QLD Health Perinatal data was so small it could be considered clinically insignificant. However, if one was searching for reasons to explain the difference, several factors are evident. Each of the factors listed below may influence data collection and interpretation:

1. Different data collection and analysis methods: data from this study consisted of primary data likewise Perinatal Data collection data was sourced directly from the districts on the Perinatal Data collection form which could be argued to also be a primary source of data, whereas data from national sources, such as the National Health Survey Queensland Health, are classified as secondary data.⁽³⁷⁾
2. The different data collected on study participants reported in our study were on women who intended to breastfeed to some degree, whereas the population reported in the National Health Survey and the Perinatal Data Collection included all births for that period of time.

Breastfeeding in an urban population

3. Chronological difference: for example, data were collected in 2004 (National) versus 2008 (Study 2 - GCH).
4. Regional data variations, e.g. the Gold Coast demographics, which are those of a transient, high density, rapidly growing population.⁽¹⁴⁴⁾
5. Variation in the definition of exclusive breastfeeding: the misinterpretation of research findings due to the inconsistency of breastfeeding definitions can be problematic.⁽¹⁵⁶⁾ The definition of breastfeeding varies between studies as well as government data collection agencies.

Chapter 4, 'Breastfeeding exclusivity and duration in an urban population', consisted of survey data about women intending to breastfeed. Several factors were identified that may influence breastfeeding exclusivity and duration. These factors included higher parity, maternal age and breastfeeding self-efficacy, each of which has been identified previously in Australian breastfeeding studies.⁽²⁶⁾ Generally, the women who breastfed longer were of higher maternal age, had greater parity, were in a relationship, and had higher levels of education. While occupation did not affect breastfeeding duration in this study, it has previously been associated with premature weaning and increased infants formula feeding.^(139, 140)

In terms of factors that may affect breastfeeding duration, our study reported similar findings to that of a longitudinal study conducted in a regional Queensland city (Toowoomba)⁽²⁹⁾, as well as other published works on breastfeeding women.^(28, 29, 46, 87, 139-144) All of these findings suggest that more experienced and confident mothers are

Breastfeeding in an urban population

likely to benefit themselves and their children by exclusively breastfeeding for extended durations.

State-wide data from both the QLD Health and Study 2, 'Breastfeeding duration and exclusivity in an urban population', reported that 59% of women continue to breastfeed until six months. Comparable six month exclusive breastfeeding rates were reported between the study in Chapter 4 (35%) and the National Health Survey (31%) in 2001.^(26, 129) In comparison, Queensland Health reported in 2008 that 59% of Queensland infants were fed breast milk to some degree at six months. This is well below the NHMRC national objective of 80% breastfeeding at six months.^(138, 145) This report also highlighted that only 13% of infants were exclusively breastfed for the first six months, again falling short of the state target of 50%.⁽¹³⁸⁾

In contrast, the Australian Longitudinal Study of 2004 reported both "full" and "any" breastfeeding of 71% at six months.^(146, 147) The Australian Longitudinal Study of children in 2008 further reported that 56% of women continued to fully and partially breastfeed until six months.^(146, 147)

Similar international data exists. A 2002 United States of America study reported exclusive breastfeeding rates of only 13% at six months.⁽¹⁴⁸⁾ A comparison of global breastfeeding duration rates including data from Study 2 on breastfeeding exclusivity and duration shows that the optimal infant nutrition target of exclusive breastfeeding for the first six months fall short at recommended guidelines. Recommendations reported by Binns ⁽¹⁴⁹⁾ in 2009 highlighted the importance of measuring breastfeeding exclusivity; not only is exclusive breastfeeding for the first six months important for

Breastfeeding in an urban population

infant nutrition, it has also been linked to infant morbidities and a reduction in associated risks. These include conditions such as Sudden Infant Death Syndrome (SIDS), obesity and type 1 diabetes, all of which are national health priorities⁽¹⁵⁰⁾.

The BSES-SF tool as a predictor for breastfeeding exclusivity and duration

Findings from this study show that the results from the 'Breastfeeding Self-Efficacy Score - SF assessment tool were statistically significant and are associated with breastfeeding initiation and duration although it was not possible to prove causation.

^(61, 150) A study by McCarter-Spaulding in 2009 used the BSES-SF tool to predict breastfeeding initiation and duration.⁽¹⁵¹⁾ Their results found that the higher levels of breastfeeding self-efficacy were predictive of longer duration and exclusive breastfeeding at one and six months postpartum. These findings are consistent with previous research conducted using the BSES-SF as a predictor to breastfeeding success.

Breastfeeding self-efficacy, as well as several other identified variables (such as the use of in-hospital formula supplementation, antenatal class attendance, and the type of delivery a women experiences) have all independently been identified as predictors of exclusive breastfeeding duration.⁽¹⁵²⁾ Findings from the BSES-SF should be used in conjunction with other known variables when used for clinical use to identify breastfeeding mothers at high risk of reduced exclusive breastfeeding and premature weaning.⁽⁶⁷⁾

Breastfeeding women's knowledge of mastitis

Our second study reported the women's knowledge of mastitis. The findings from this survey data, highlighted the varying degree of mastitis knowledge in this cohort of breastfeeding women.⁽⁷⁴⁾ The use of open-ended questions in our questionnaire gave the participants the opportunity to provide answers, in their own words, without the constraint of fixed possibilities. Most women identified mastitis with infection and pain, and reported symptoms such as blocked ducts, inflammation and flu-like symptoms including pain, fever and feeling unwell. Women also reported that they, or a friend or family member, had previously experienced symptoms of mastitis when breastfeeding.

Women, who experienced breastfeeding problems such as mastitis, reported managing the condition themselves or initially seeking advice from peers, family members or other people in their support network instead of seeking medical advice. The second most popular treatment was to access a library, books, magazines and the media or other electronic resources. Only when symptoms worsened or did not improve did women report seeking the advice of health care professionals such as their GP, midwife, or lactation consultant. The delay in the resolution of mastitis may result in premature weaning.⁽¹⁵⁴⁾ Management of mastitis at this late stage needs to be appropriate and accurate to prevent premature weaning and other complications such as abscess formation

Breastfeeding in an urban population

Findings from this study, as with that of others previously, highlights the importance of appropriate education and information from GPs, midwives, lactation consultants and other health care professionals. ^(20, 155-158)

In hindsight, it would have been beneficial to ask women when they would go to their GP for advice or treatment. A recent study⁽¹⁵⁷⁾ reported that the promotion and support of breastfeeding as the normal method of infant feeding is an important role of the GP. Traditionally, breastfeeding education and support was considered the role of the midwife or lactation consultant.⁽¹⁵⁷⁾ In contrast, the responses to Question 2 of this survey 'How do you treat mastitis' suggest that the majority of women would visit the GP only when confronted with advanced breastfeeding or lactation related problems.

This and previous work support the need for all health care professionals to be well educated and up to date with the management and expected government benchmarks for breastfeeding in Australia.⁽¹⁵⁹⁾ In 2009, Brodribb highlighted the fact that women with breastfeeding problems, especially rural women, will visit their GPs when they encounter breastfeeding problems or difficulties.⁽¹⁵⁷⁾ This further emphasises the important role that GPs play in the management of health related issues in mothers with lactation problems.⁽¹⁵⁷⁾ Brodribb further discussed that GPs often have difficulties advising women with regards lactation problems, although they recognise the benefits of breastfeeding.⁽¹⁵⁷⁾ This could be attributed in part to the limited breastfeeding education opportunities for general practitioners and the need for more recognised formal training in this area.⁽¹⁵⁷⁾

Breastfeeding in an urban population

Effect of interventions on the incidence of mastitis in the postnatal period

The third study consisted of a Cochrane Systematic Review, which was conducted to assess the effect of interventions for the prevention of mastitis in the postnatal period for breastfeeding women. Following analysis of all the searched trials, no interventions were found to significantly reduce the incidence of mastitis.

This Cochrane Systematic review did, however, highlight several issues with studies that had been conducted in this area. Studies did not find a statistically significant difference between interventions and controls. This could have been a result of several research design problems identified including adherence rates, inadequate power and intervention robustness.

While adherence rates were only reported in three of the five studies analysed, strategies were identified that could be implemented to improve adherence. These included extended consultation time with participants at recruitment to explain and reinforce instruction, designing interventions with realistic regimes (for example, tailoring drug regimens to patient lifestyle), frequent follow-up when initialising or changing treatment regimes, and the use of reminder calls and alerts to keep participants focused.

Findings also illustrated that sample size, the timing of an intervention and data collection need to be relevant to the participants, the condition measured and the outcomes expected. Moreover, the question could be raised that interventions including education and breastfeeding advice may have been more effective had they been delivered on an ongoing basis, rather than single consultations. In general, study

Breastfeeding in an urban population

design and quality was poor in all studies analysed. This review highlights the need for better planning and design to improve trial quality in this area.

In conclusion, there was insufficient evidence to show effectiveness of any of the interventions. Attention was drawn to the need for adequately powered randomised trials in this area, as we currently rely on clinical studies such as cohort and observational studies when developing breastfeeding policies.

Limitations of the first two studies in this thesis

The first study on the prevalence of breastfeeding at the Gold Coast Hospital encountered challenges with regards to the transcription of data from the maternity unit's patient daybook as this was very time consuming and required diligence with maintaining accuracy of data recording. This limitation was a result of the lack of a formal electronic recording system for this type of data at this establishment.

Variables such as smoking ethnicity and bed-sharing are known factors that affect breastfeeding initiation, duration and exclusivity.^(29, 30) Data collected on these variables would have provided a more comprehensive demographic profile of the participants in this study. Further research into this area of interest should be designed to collect and report this data. The second study examined breastfeeding exclusivity and duration in an urban population, a representative subgroup of the first study. It would have been preferable to continue to collect data past 6 months, as the analysis was limited to this finite assessment period. Moreover, ongoing data would have provided valuable longitudinal data on breastfeeding exclusivity and duration.

Breastfeeding in an urban population

Limitations to this study included difficulties concerning the recruitment of participants. Specifically, limited time allocation and constraints of access to potential participants existed within the maternity unit. Time allocated to recruit participants was restricted to 4 hours a day so as not to cause disruption to the ward activities. Due to the logistics of recruitment, it was also not feasible to recruit on weekends. Again, this limited access may have resulted in the potential loss of suitable participants into the study, which may have altered the overall demographics of the participants. Further exploration of the pilot data from the questions around mastitis knowledge (e.g. focus group discussion) may have benefited from opportunity for participants to discuss issues around each question.

Summary of recommendations from studies

Study 1 and 2 in this body of work has provided data on breastfeeding prevalence, exclusivity and duration in a cohort of women who gave birth at the Gold Coast hospital during the study period. As this data has not been previously isolated from state-wide data, it also contributed to the body of knowledge surrounding breastfeeding in this Australian urban population.

While collecting data for the first two studies we identified that the procedure for data collection between the maternity ward and data collection unit at Gold Coast Hospital could be simplified and improved. Finally, we also collected unique pilot data on women's knowledge of mastitis and treatment of this condition and systematically reviewed the literature on interventions to prevent this condition.

Breastfeeding in an urban population

On review of the literature, longitudinal data on breastfeeding exclusivity and duration is limited and this body of work identified the following:

1. The second study has highlighted the need for a universal definition of both breastfeeding and mastitis; this has also been acknowledged in other studies. As a result of the lack of consistency when defining the prevalence of exclusivity within breastfeeding studies and government data collection, the discrepancy with results has highlighted the need to standardise these definitions. As highlighted by both the studies, as well as Binns in 2009,⁽¹⁴⁹⁾ the need for consistency with regards to definitions for breastfeeding and related complications such as mastitis would strengthen the validity of studies when comparing results between studies.
2. Although the participants for the Gold Coast Hospital study in 2008 intended to exclusively breastfeed for six months, findings reported were similar to results reported by QLD Health perinatal data statistics and the ALS, which fall short of the NHMRC target of exclusive breastfeeding until 6 months. This work therefore reinforces, at a regional (Gold Coast) level, the need for further research into breastfeeding exclusivity and duration.
3. It is unclear from the systematic review whether the included studies are underpowered, or whether there is a need for alternative interventions, which may be more effective in preventing mastitis.

Recommendations for clinical practice

Data storage in health facilities is primarily to support clinical practice. As clinicians become increasingly mindful of the need for evidence-based practice, data collection and method of storage will develop to benefit its multipurpose value. Both the studies in this work have highlighted the need for improvements in the following areas. Firstly, the limitations in data collection and management identified in the first study were related to medical records within a large healthcare facility. The primary purpose of medical records is to facilitate clinical treatment of patients, not to provide research data. Therefore, data were missing and had to be transcribed from different sources and were unable to be linked as a result of this process. Electronic data collection and record keeping for clinical practice would lessen the challenges that influence current clinical data management. Education and adequate support of clinical staff to streamline the recording and management of data would assist future research, and facilitate the cross examination of demographic and clinical variables of potential study participants.

The third study highlighted that there is insufficient evidence in the literature to show effectiveness of any of the interventions to prevent mastitis, which has implications for clinical practice and further research. Until research design of randomised trials is improved, we will continue to rely on clinical studies, such as cohort and observational studies, when developing breastfeeding policies.

Breastfeeding in an urban population

The second and third studies highlighted the need for universal definitions for breastfeeding and mastitis. The need for standardised definitions and terminologies within studies for topics such as breastfeeding and mastitis may improve the quality of research in these areas, allowing for meaningful comparisons of data, which would also be helpful when reviewing studies. Practitioners depend on research to support evidence-based practice, therefore relying on the accuracy of terminology and standard definitions in the process of weighing the probability of one disease versus that of other diseases. This is especially pertinent when assessing severity of symptoms, when making differential diagnosis and treatments. Variation in this may lead to discrepancies diagnosing and the treatment of patients.

Finally, this thesis has highlighted the importance of further research into improving breastfeeding exclusivity and duration rates. Findings from Study 1 and 2 have reinforced known facts that breastfeeding initiation in Australia is high but breastfeeding exclusivity and duration rates fall short of national targets. Both Study 1 and 2 have provided unique data on breastfeeding rates from the Gold Coast Health Service. Study 2 has also provided pilot data on the knowledge of mastitis from a cohort of breastfeeding women, clearly showing the need for continuing research in this area. Findings from the Cochrane Systematic Review conducted have made an original contribution to the body of literature in this area. The Cochrane Systematic Review has also identified the need for ongoing research into mastitis as it found a need for the development of robust and creative interventions into the prevention of mastitis.

Appendices

Appendix 1: Questionnaire

Prior to commencing this questionnaire, you will be given a plain language statement about the study and will be asked to fill in a consent form. At all times the information you share will remain confidential and your privacy will be protected. The questionnaire will ask you questions about your demographic details, pregnancy, birth, breastfeeding knowledge and where you get advice regarding breastfeeding and mastitis. Some questions require you to give a longer answer than others; some questions need you to answer the question by placing a circle around a Yes or No, or ticking the correct answer.

ID number _____

1. Name _____

2. Mother's date of birth _____

3. Mother's Age _____

4. Address _____

5. Postcode _____

6. Home phone _____

7. Mobile phone _____

8. Infants name _____

Breastfeeding in an urban population

9. Infants date of birth (_/ _/ _)

10. What is the highest level of education you have completed, (Please tick one box only)	
Completed year 10 or less	
Completed up to year 12	
Trade diploma TAFE	
Bachelor degree of higher	
11. Which option best describes your occupation: (please tick one box only if these choices are not suitable please record your occupation beside other)	
Nil paid employment	
Self-employed & business owners	
Tradesperson & labourers	
Clerical & service workers	
Managers & administrators	
Professionals & associate professionals	
12. Marital status: (Please tick the most appropriate response)	
1. Never married	
2. Widowed	
3. Divorced	
4. Separated	
5. Married	
6. Defacto	

Breastfeeding in an urban population

13. How many live infants have you had including this new infant?

14. What is mastitis? _____

15. How do you treat mastitis? _____

16. Where did you find out this information? _____

BF Intention: How do you plan to feed this infant? (Please tick the most accurate response)		
17. I intend to fully breastfeeding this infant	YES	NO
18. I intend to breastfeed and formula feed this infant	YES	NO
19. I intend to express breast milk and infants feeding	YES	NO
Do you intend to (Please tick the most accurate response)		
20. Demand feed	YES	NO
21. Scheduled feed	YES	NO

Thank you for your participation in this study. You will be contacted by telephone in 4 weeks for your follow-up questionnaire.

Breastfeeding in an urban population

Appendix 2: Breastfeeding Self-Efficacy Scale (BSES)

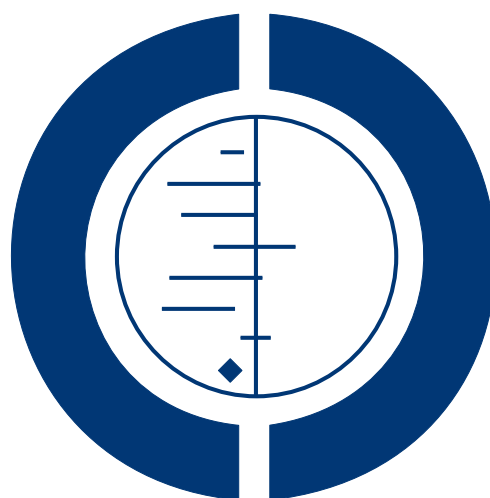
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For each of the following statements, please choose the answer that best describes how confident you are with breastfeeding your new infant. Please mark your answer by circling the number that is closest to how you feel. There is no right or wrong answer.		1	2	3	4	5
1 = not at all confident, 2 = not very confident, 3 = sometimes confident, 4 = confident, 5 = very confident						
1	I can always determine that my baby is getting enough milk					
2	I can always successfully cope with breastfeeding like I have with other challenging tasks					
3	I can always breastfeed my baby without using formula as a supplement					
4	I can always ensure that my baby is properly latched on for the whole feeding					
5	I can always manage the breastfeeding situation to my satisfaction					
6	I can always manage to breastfeed even if my baby is crying					
7	I can always keep wanting to breastfeed					
8	I can always comfortably breastfeed with my family members present					
9	I can always be satisfied with my breastfeeding experience					
10	I can always deal with the fact that breastfeeding can be time consuming					
11	I can always finish feeding my baby on one breast before switching to the other breast					
12	I can always continue to breastfeed my baby for every feeding					
13	I can always manage to keep up with my baby's breastfeeding demands					
14	I can always tell when my baby is finished breastfeeding					

Appendix 3: Cochrane Systematic Review

Interventions for preventing mastitis after childbirth (Review)

Crepinsek MA, Crowe L, Michener K, Smart NA



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TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	2
OBJECTIVES	4
METHODS	4
Figure 1.	6
Figure 2.	7
RESULTS	9
DISCUSSION	10
AUTHORS' CONCLUSIONS	12
ACKNOWLEDGEMENTS	12
REFERENCES	12
CHARACTERISTICS OF STUDIES	16
DATA AND ANALYSES	26
Analysis 1.1. Comparison 1 Antibiotic versus no antibiotic, Outcome 1 Mastitis.	28
Analysis 2.1. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 1 Mastitis.	29
Analysis 2.2. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 2 Sore nipples.	30
Analysis 2.3. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 3 Breast engorgement.	31
Analysis 2.4. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 4 Exclusive breastfeeding.	32
Analysis 2.5. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 5 Breastfeeding problems, mean per mother.	33
Analysis 3.1. Comparison 3 Anti-secretory factor in cereal versus standard cereal, Outcome 1 Mastitis.	33
Analysis 3.2. Comparison 3 Anti-secretory factor in cereal versus standard cereal, Outcome 2 Mastitis recurrence.	34
Analysis 4.1. Comparison 4 Mupirocin ointment versus breastfeeding advice alone, Outcome 1 Mastitis.	34
Analysis 5.1. Comparison 5 Fusidic acid ointment versus breastfeeding advice alone, Outcome 1 Mastitis.	35
Analysis 6.1. Comparison 6 Mupirocin ointment+BF advice versus fusidic acid ointment+BF advice, Outcome 1 Mastitis.	35
APPENDICES	35
HISTORY	37
CONTRIBUTIONS OF AUTHORS	37
DECLARATIONS OF INTEREST	38
SOURCES OF SUPPORT	38
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	38

[Intervention Review]

Interventions for preventing mastitis after childbirth

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ABSTRACT

Background

Despite the health benefits of breastfeeding, initiation and duration rates continue to fall short of international guidelines. Many factors influence a woman's decision to wean; the main reason cited for weaning is associated with lactation complications, such as mastitis.

Objectives

To assess the effects of preventive strategies for mastitis and the subsequent effect on breastfeeding duration.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (November 2009), CENTRAL (*The Cochrane Library* 2009, Issue 4), MEDLINE (1950 to November 2009), EMBASE (1974 to November 2009), CINAHL (1981 to November 2009), MIDIRS (1971 to November 2009), IPA (1970 to November 2009), AMED (1985 to November 2009) and LILACS (1982 to November 2009).

Selection criteria

We included randomised controlled trials of interventions for preventing mastitis in postpartum breastfeeding women.

Data collection and analysis

We independently identified relevant studies and assessed the trial quality. We contacted trial authors for missing data and information as appropriate.

Main results

We included five trials (involving 960 women). In three trials of 471 women, we found no significant differences in the incidence of mastitis between use of antibiotics and no antibiotics (risk ratio (RR) 0.43; 95% confidence interval (CI) 0.11 to 1.61; or in one trial of 99 women comparing two doses (RR 0.38; 95% CI 0.02 to 9.18). We found no significant differences for mastitis in three trials of specialist breastfeeding education with usual care (one trial); anti-secretory factor cereal (one trial); and mupirocin, fusidic acid ointment or breastfeeding advice (one trial).

Generally we found no differences in any of the trials for breastfeeding initiation or duration; or symptoms of mastitis.

Interventions for preventing mastitis after childbirth (Review)

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I

Authors' conclusions

There was insufficient evidence to show effectiveness of any of the interventions, including breastfeeding education, pharmacological treatments and alternative therapies, regarding the occurrence of mastitis or breastfeeding exclusivity and duration. While studies reported the incidence of mastitis, they all used different interventions. Caution needs to be applied when considering the findings of this review as the conclusion is based on studies, often with small sample sizes. An urgent need for further adequately powered research is needed into this area to conclusively determine the effectiveness of these interventions.

PLAIN LANGUAGE SUMMARY

Interventions for the prevention of mastitis following childbirth

Healthcare authorities and the World Health Organization recommend that newborn infants should exclusively be given breast milk until they are six months of age. Breastfeeding provides health benefits for the infant, including improved nutrition and protection against illnesses such as gastroenteritis, respiratory and ear infections, urinary tract infections, allergies and diabetes mellitus. Breastfeeding also saves on costs and has benefits for the mother. Mastitis is a significant complication of lactation and may stop some mothers from breastfeeding. The nipple becomes sore and the breast tender and swollen. If the nipple cracks, the breast can become infected and the mother may experience flu-like symptoms. Poor breast attachment and inadequate emptying of milk from the breast when feeding may contribute to developing mastitis. It is important to investigate preventive measures in order to maintain and increase breastfeeding exclusivity and duration.

This review found five randomised controlled trials that involved a total of 960 women. They looked at a variety of preventive interventions including breastfeeding education, taking antibiotic medication, topical ointments and anti-secretory factor cereal. None of the therapies made any difference in reducing breast infections or the length of breastfeeding exclusivity and duration with this limited evidence. Generally studies were of low quality, with limited findings highlighting the need for better quality research in this area.

BACKGROUND

The World Health Organization (WHO) recognises the short and long-term benefits of breastfeeding and recommends exclusive breastfeeding until six months of age ([Kramer 2002](#); [World Health Organization 2008](#)). The epidemiologic evidence overwhelmingly supports breastfeeding as being protective of infant, maternal, family and community health ([Kramer 2002](#); [World Health Organization 2008](#)). The improved nutrition, immunological, psychological, economical and environmental benefits that breastfeeding provides are well documented ([Chezem 2003](#)). Specifically, breast milk protects infants and children against conditions such as gastroenteritis and respiratory infections ([MacDonald 2003](#)); moreover babies who are not breastfed are predisposed to many health complications in later life, including high blood pressure, obesity, non-insulin dependent diabetes and ischaemic heart disease ([Thompson 2005](#)). The short- and long-term benefits of breastfeeding to the mother include the increase of uterine contractions post delivery, resulting in a reduction of postpartum bleeding ([Chua 1994](#)). Breastfeeding also enhances a faster return to the pre-pregnant body weight ([Dewey 1999](#)), as well as pos-

sible protection against osteoporosis, ovarian and uterine cancer ([Cummings 1993](#); [Melton 1993](#); [Rosenblatt 1993](#); [Siskind 1997](#)).

Despite the recognised health, emotional, psychosocial and societal benefits of breastfeeding to women and children, breastfeeding rates worldwide are sub-optimal, especially among low-income women. Increasing breastfeeding initiation and duration amongst low-income women would not only offer improved health benefits to both the mother and infant, but would lessen the economic burden experienced by this group of people within the community ([Guttman 2000](#); [Mitra 2004](#)).

Description of the condition

There are many factors that may influence a woman's decision to cease breastfeeding. However, the main reason cited for stopping breastfeeding is related to complications of lactation ([Dener 2003](#)). Mastitis is a significant complication and is a common problem in lactating women ([Dener 2003](#)). Mastitis is a debilitating condition and may contribute to weaning in the first three weeks ([Schwartz](#)

2002). Mastitis has been reported as the third most common reason for weaning (Fetherston 1997), with one in four breastfeeding women citing mastitis as the reason they weaned (Michie 2003).

The definition of mastitis varies throughout the literature; the WHO defines mastitis as “an inflammatory condition of the breast, which may or may not be accompanied by infection” (Fetherston 1998; Inch 2000; World Health Organization 2008). Non-infective mastitis may result from milk stasis, blocked ducts, engorgement or physical injury to the breast. Infective mastitis may result from cracked or traumatised nipples; interruption in the nipples’ integrity provides a route for micro-organisms to enter the breast (Fetherston 1998). Mastitis can be viewed as a continuum of disease, from non-infective inflammation of the breast to infection that may lead to abscess formation. Mastitis presents with a plethora of clinical symptoms; it can present unilaterally or bilaterally with breast pain, redness and swelling; and may be associated with flu-like symptoms (Jahanfar 2009). The type of mastitis experienced may affect the duration of symptoms, from two to three days to as long as 14 days or more (Thomsen 1984). The prevalence of mastitis varies depending on the definition and the number of weeks postpartum (Kinlay 2001; Potter 2005; Semba 2000). Studies following participants from three to 12 months have reported incidence rates of mastitis of 23.7% to 27.1% (Fetherston 1998; Vogel 1999), while the recurrence of mastitis is between 6.5% and 8.5% (Fetherston 1997; Vogel 1999).

Description of the intervention

Health education and peer support have been identified as interventions that improve the initiation of breastfeeding amongst low-income populations where breastfeeding initiation rates are typically low (Dyson 2005). However antenatal breastfeeding education has been explored as an intervention to improve breastfeeding duration rates (Lumbiganon 2007). The literature also suggests that education, along with correct breastfeeding practices, leads to improved breastfeeding exclusivity and duration (Fetherston 1998; Inch 2006; Potter 2005) and one study has postulated that breastfeeding education may positively impact on the prevention of mastitis (Flores 2002). Poor breast attachment and inadequate breast drainage when feeding are issues that have been linked to women developing mastitis (Bell 1998; Inch 2006). Breastfeeding frequently, alternating the breast that feeds are started from, and the position used to feed the infant, may all help to relieve engorgement. Breast compression or breast massage before latching is an effective way to avoid blocked ducts that may lead to mastitis. Frequent feeding and the use of electric or hand pumps may assist by efficiently emptying the breast, and reduce breast engorgement and milk stasis. Previous work has suggested that if left untreated, these conditions may develop into mastitis (Foxman 2002). Avoiding the use of ill-fitting clothes or bras and sleeping on the stomach are among other measures that women can take to reduce pres-

sure on breast tissue. Such pressure can lead to blocked milk ducts or traumatised breast tissue, which is another precursor to mastitis. Taking care of oneself, getting plenty of rest, adequate fluids and a nutritious diet are all seen as preventive treatments to help manage maternal stress and fatigue, which are factors seen to precede mastitis (Riordan 1990; Spowart 2004). Studies by Roberts 1998 have shown that cabbage leaves can be used to help manage engorgement by reducing pain and discomfort. Antibiotics have also been used as a preventive treatment for women that are predisposed to recurrent mastitis (Fetherston 1998; Foxman 1994; Jahanfar 2009). However there is insufficient evidence to confidently support that antibiotics therapy is effective in the management of mastitis (Jahanfar 2009).

How the intervention might work

Interventions discussed in this review are aimed at preventing mastitis. The interventions reviewed potentially may reduce the incidence and recurrence of mastitis. Interventions reviewed include the following:

- breastfeeding education; to improve patient understanding of breastfeeding physiology and management;
- breast massage before and during breastfeeding; to facilitate milk extraction from the breast, and to soften breast tissue when draining the breast of milk;
- frequency of breastfeeding; to facilitate adequate breast emptying;
- alternating breasts with feeds; to facilitate adequate breast emptying;
- use of heat packs before and cold packs after breastfeeding; to reduce engorgement and inflammation as well as facilitate the drainage of milk from the breast;
- correct positioning of baby at the breast; to reduce the risk of nipple damage as well as facilitate adequate drainage of milk from the breast
- relaxation, stress and fatigue management; to provide support and basic education on parenting coping mechanisms to mothers;
- use of prophylactic antibiotics; to manage recurrence of mastitis;
- breast emptying either by feeding or the use of hand/electric pump; to facilitate adequate emptying of the breast which will reduce the risk of engorgement and mastitis.

Why it is important to do this review

Currently, a variety of interventions are recommended for the prevention of mastitis following childbirth, and to improve breastfeeding outcomes including increase of breastfeeding initiation, exclusivity and duration, as well as improving maternal satisfaction and confidence (Dennis 2008; Dyson 2005; Jahanfar 2009;

[Kramer 2002](#); [Lumbiganon 2007](#)). Interventions for the resolution or reduction of mastitis including antibiotics and the treatment of painful nipples with mastitis as an outcome measure have been reviewed and published ([Dennis 2008](#); [Jahanfar 2009](#)).

OBJECTIVES

Primary

To assess the effectiveness of preventive strategies (for example, breastfeeding education, pharmacological treatments and alternative therapies) on the occurrence or recurrence of non-infective or infective mastitis in breastfeeding women post childbirth.

Secondary

To evaluate the effects of interventions to prevent mastitis on breastfeeding duration and exclusivity.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) with the purpose of evaluating one or more interventions to prevent mastitis.

Types of participants

Postpartum women, either primiparous or multiparous, who are breastfeeding or who intend to breastfeed both exclusively and partially. We also included women who have had mastitis previously.

Types of interventions

Any intervention versus any other intervention or no intervention (placebo).

Types of interventions may include:

- breastfeeding education;
- breast massage before and during breastfeeding;
- frequency of breastfeeding;
- alternating breasts with feeds;
- use of heat packs before and cold packs after breastfeeding;

- correct positioning of baby at the breast;
- relaxation, stress and fatigue management;
- use of prophylactic antibiotics;
- breast emptying either by feeding or the use of hand/electric pump.

Types of outcome measures

We considered trials if they included one or both of the following primary outcomes.

Primary outcomes

1. Incidence of mastitis.
2. Recurrence of mastitis.

Secondary outcomes

1. Symptoms as reported by the women.
2. Length of time breastfeeding.
3. Duration of exclusive breastfeeding.
4. Duration of any breastfeeding.
5. Maternal breastfeeding satisfaction.
6. Maternal breastfeeding confidence.

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (November 2009).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the [Cochrane Pregnancy and Childbirth Group](#).

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search

Coordinator searches the register for each review using the topic list rather than keywords.

In addition, we searched the CENTRAL (*The Cochrane Library* 2009, Issue 4), MEDLINE (Ovid) (1950 to November 2009), EMBASE (Elsevier) (1974 to November 2009), CINAHL (1981 to November 2009), MIDIRS (Ovid) (1971 to November 2009), IPA (Ovid) (1970 to November 2009), AMED (1985 to November 2009) and LILACS (Latin American and Caribbean Center on Health Sciences Information) (1982 to November 2009) using the search strategies detailed in [Appendix 1](#).

We did not apply any language restrictions.

Data collection and analysis

The Trials Search Co-ordinator performed the main search for this review. Keryl Michener (Librarian) conducted an additional search and performed the initial sorting of suitable studies. We retrieved full text of relevant studies. If the retrieved articles were non-English, we obtained a partial English translation of the methods and results only. Two review authors Maree Crepinsek (MC) and Neil Smart (NS) independently examined the retrieved articles to assess whether they satisfied the inclusion criteria. We resolved disagreement through discussion.

Selection of studies

We retrieved the full manuscript of all studies included in this review. Two review authors independently assessed for inclusion all potential studies that we identified as a result of the search strategy. We resolved any disagreement through discussion when required. Two review authors (MC and NS) independently assessed the titles and abstracts of identified studies. Where we could not make a clear decision on the basis of the title or abstract, we retrieved the full manuscript and reviewed our decision.

Data extraction and management

We designed a data extraction form to manage the data. Two review authors extracted data from each study using a summary of quality assessment. The chief investigator then transcribed the relevant data to Review Manager ([RevMan 2008](#)). Two review authors, MC and Linda Crowe (LC) extracted the data of eligible studies using the agreed data extraction form. We resolved discrepancies through discussion with a third review author (NS). We addressed any discrepancies by consensus. We entered data using RevMan ([RevMan 2008](#)) and checked for accuracy. When information regarding any of the above was unclear, we attempted to contact the authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2008](#)). We resolved any disagreement by discussion or by involving a third assessor. We assessed sequence generation, allocation sequence concealment, blinding, incomplete outcome data, selective outcome reporting using the standard 'Risk of bias' table using the following subjective judgements regarding protection from bias. We used the Cochran-Mantel-Haenszel method for risk ratio.

- Yes - low risk of bias.
- Unclear - moderate risk of bias.
- No - high risk of bias.

(1) Sequence generation (checking for possible selection bias)

We described each included study using the following method to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We assigned a quality score for each trial, using the following criteria (See [Figure 1](#); [Figure 2](#)).

Figure 1. Summary of quality assessment of included studies. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.

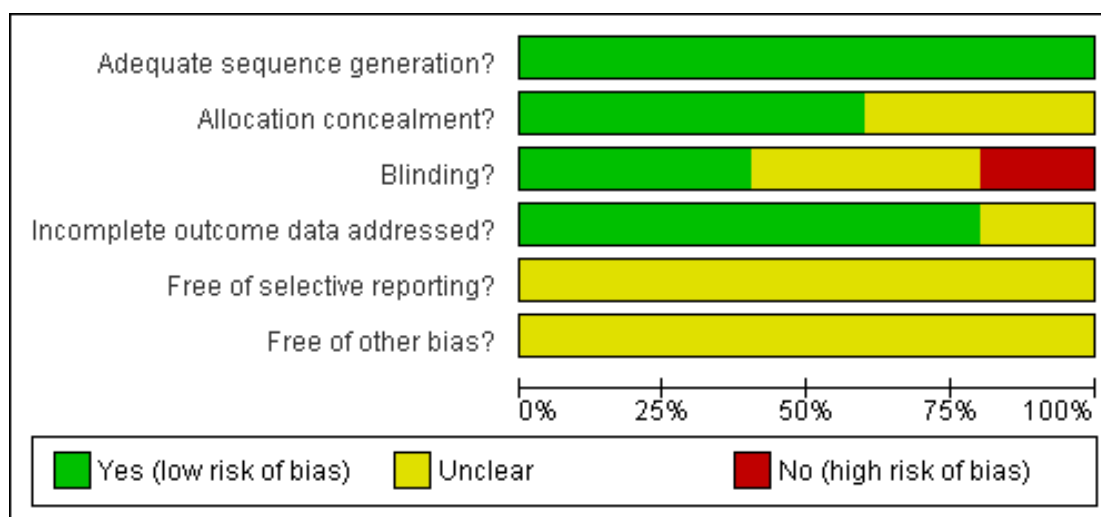


Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study.

	Adequate sequence generation?	Allocation concealment?	Blinding?	Incomplete outcome data addressed?	Free of selective reporting?	Free of other bias?
Amir 2004	+	+	+	+	?	?
De Oliveira 2006	+	?	?	+	?	?
Livingstone 1999	+	+	-	+	?	?
Sebitloane 2008	+	+	?	?	?	?
Svensson 2004	+	?	+	+	?	?

We assessed the method as:

- yes - adequate (any truly random process, e.g. random number table; computer random number generator);
- no - inadequate (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear.

We intended to include quasi-RCTs in this review, but as none were able to be included, we did not conduct a sensitivity analysis as originally planned.

(2) Allocation concealment (checking for possible selection bias)

We describe for each included study the method used to conceal the allocation sequence in sufficient detail and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- yes - adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- no - inadequate (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear.

(3) Blinding (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We judged studies at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results.

We assessed the methods as:

- yes - adequate;
- no - inadequate; or
- unclear for participants, personnel or outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We described for each included study, and each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed completeness to follow up using the following criteria:

- adequate (e.g., where there was no missing data or where reasons for missing data are reported between the two groups);
- inadequate (e.g., where missing data are likely to be related to outcomes or are not balanced across groups, or where high levels of missing data are likely to introduce serious bias or make the interpretation of results difficult);
- unclear (e.g., where there is insufficient reporting of attrition or exclusions to permit a judgement to be made).

(5) Selective reporting bias

We described each included study, how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- yes - adequate (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- no - inadequate (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear.

(6) Other sources of bias

We described for each included study any important concerns we had about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we consider it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses if required. This review did not require a sensitivity analysis.

Measures of treatment effect

We analysed results separately in five of the studies, as the interventions listed were very different and, in the opinion of our statistician, could not reasonably be combined into a comparison of 'any intervention'. We carried out statistical analysis using the Review Manager software ([RevMan 2008](#)).

Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

Continuous data

For continuous data, we used mean difference if outcomes were measured in the same way between trials. We also used the standardised mean difference to combine trials that measure the same outcome, but used different methods.

Dealing with missing data

For included studies, we noted levels of attrition. We had planned to explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

We analysed data on all participants available in the group to which they were allocated, regardless of whether or not they received the allocated intervention. When analysing the seven studies, six were unclear when reporting missing data.

Assessment of heterogeneity

Where we found substantial heterogeneity ($I^2 > 50\%$), we intended to explore potential sources including differences in study quality, inclusion criteria or intervention regimens between studies, and use a random-effects meta-analysis as an overall summary if considered appropriate (Deeks 2001).

Assessment of reporting biases

Where we suspect reporting bias, we attempted to contact study authors asking them to provide missing outcome data. Where this was not possible, and the missing data were thought to introduce serious bias, we planned to explore the impact of including such studies in the overall assessment of results by a [Sensitivity analysis](#).

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2008). In future updates of this review, where we suspect clinical or methodological heterogeneity between studies sufficient to suggest that treatment effects may differ between trials, we will use random-effects meta-analysis. If we identify substantial heterogeneity in a fixed-effect meta-analysis, we plan to note this and repeat the analysis using a random-effects method.

Subgroup analysis and investigation of heterogeneity

We planned to conduct sub-group analysis on the effects of interventions based on the incidence of mastitis being recurrent or primary if necessary. We carried out no sub-group analysis in this review, although we combined three studies due to the discrete nature of the interventions, and found no significant heterogeneity.

Sensitivity analysis

None of the studies reviewed required a sensitivity analysis relevant to this review. We did not conduct a sensitivity analysis, excluding studies with inadequate allocation concealment, as there were sufficient data to pool for only one outcome (three trials, all with adequate allocation concealment).

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#); [Characteristics of studies awaiting classification](#); [Characteristics of ongoing studies](#).

Results of the search

The search strategy protocol generated 1029 article 'hits'. After screening titles and abstracts, we discarded all but 38 articles, of which we excluded 32 as they did not meet the inclusion criteria as outlined by the protocol. We included five trials; one study (Gensch 2006) is still awaiting classification (information on this study was not available at the time of the review, so we will review it at a later date).

Included studies

See [Characteristics of included studies](#).

Interventions

Of the five trials that met the pre-stated inclusion criteria in this review, three trials used antibiotic treatments (Amir 2004; Livingstone 1999; Sebitloane 2008), and one trial evaluated breastfeeding education (De Oliveira 2006). One trial compared basic breastfeeding advice in combination with topical treatments - this trial also included an antibiotic arm (Livingstone 1999). The four arms of the Livingstone 1999 trial were: optimal breastfeeding advice ($n = 23$); topical 2% mupirocin ointment applied to the nipples ($n = 25$); topical fusidic acid ointment applied to the nipples ($n = 17$); oral antibiotics - cloxacillin/erythromycin ($n = 19$). We entered data from this trial as both separate arms and combined arms, but in all cases we avoided double counting and inappropriate totaling.

One trial evaluated anti-secretory factor in cereal. Anti-secretory factor is a protein found in most human tissue including the placenta and possibly occurring in milk, which has been shown to have possible anti-infectious and anti-inflammatory capabilities (Svensson 2004).

Outcomes

All five trials reported the primary outcome, incidence of mastitis, with one trial also reporting mastitis recurrence.

The secondary outcome of symptoms reported by women was reported as sore nipples or nipple pain in two trials, and breast engorgement in one trial.

Breastfeeding outcomes were addressed in two trials. Exclusive breastfeeding was reported in two trials and any breastfeeding, breastfeeding problems or perceived low milk supply were each addressed in a single trial.

Excluded studies

See [Characteristics of excluded studies](#).

We excluded 32 studies, mostly because the trials in question were not aimed at preventing mastitis, or were not RCTs.

Risk of bias in included studies

There were no quasi-randomised trials included in this review; therefore we did not conduct a sensitivity analysis as originally planned.

Allocation

All five included trials reported adequate sequence generation methods. Three trials also reported adequate methods for concealing randomisation, with the remaining two trials judged to have an unclear risk of bias in regard to allocation concealment.

Blinding

Two trials were blinded (Amir 2004; Svensson 2004) but due to the nature of the interventions, it was not feasible to completely blind in two of the trials (De Oliveira 2006; Sebitloane 2008). The remaining trial was an open, unblinded study (Livingstone 1999).

Incomplete outcome data

The study by Amir reported complete data on all participants (Amir 2004) but this study was stopped prematurely. Only one study reported having no loss of participants (Livingstone 1999). One study reported a loss to follow up ranging between 5% and 9.9% (De Oliveira 2006), the remaining two studies reported loss to follow up greater than 20% (Sebitloane 2008; Svensson 2004).

Selective reporting

It was not possible to be clear if any of the trials had avoided selective reporting.

Other potential sources of bias

It was not possible to be clear if any of the trials were free of other sources of bias. For instance, two trials were stopped early (Amir 2004; Livingstone 1999).

Effects of interventions

Primary outcome: mastitis

None of the interventions evaluated were able to demonstrate a significant effect on preventing mastitis. We found no evidence of heterogeneity among studies that we compared.

- In three trials (of 471 women) comparing antibiotics with no antibiotics, the risk ratio (RR) for mastitis was 0.43 95% confidence interval (CI) 0.11 to 1.61 (Analysis 1.1). (Two of the three trials compared antibiotics with placebo (Amir 2004 used

flucloxacillin; and Sebitloane 2008 used intravenous cefoxitin in HIV infected women. In the other trial, Livingstone 1999 (n = 84) had four arms to this trial comparing oral cloxacillin/erythromycin with mupirocin or fusidic acid ointment, or with breastfeeding advice alone).

- In a trial of 211 women where specialist breastfeeding education was compared with usual care (De Oliveira 2006), there were no cases of mastitis in either group when the women were discharged from hospital; at seven days follow up the RR of mastitis was 3.75; 95% CI 0.35 to 40.70 and at 30 days the RR was 0.93; 95% CI 0.17 to 4.95 (Analysis 2.1).

- In a trial of 29 women comparing consumption of anti-secretory factor cereal with standard cereal (Svensson 2004), the RR of mastitis was 0.24; 95% CI 0.03 to 1.72 (Analysis 3.1).

- In Livingstone 1999, neither mupirocin or fusidic acid ointment were shown to be more effective than specialist breastfeeding advice alone (48 and 40 women respectively; Analysis 4.1 and Analysis 5.1) and no differences in mastitis rates were seen between mupirocin and fusidic acid (42 women; Analysis 6.1).

One trial (Svensson 2004) also reported recurrence of mastitis within five weeks, finding no significant difference between the group consuming anti-secretory factor cereal and the group consuming standard cereal (29 women; Analysis 3.2).

Secondary outcomes

Symptoms

In a trial of 211 women comparing breastfeeding education with usual care (De Oliveira 2006), we found no significant differences for sore nipples (Analysis 2.2) or breast engorgement (Analysis 2.3).

Breastfeeding

We found no significant differences in the rate of exclusive breastfeeding when we compared specialist breastfeeding education with usual care in one trial of 210 women (De Oliveira 2006; Analysis 2.4). De Oliveira 2006 reported a mean of about three breastfeeding problems per mother in both groups at 30 days follow up (Analysis 2.5).

DISCUSSION

The five studies of this review all measured 'incidence of mastitis'; one study reported recurrence of mastitis and duration of exclusive or any breastfeeding, and none of the studies reviewed measured breastfeeding pain. This review also identified several factors that

are study limitations and therefore impact on study quality. Common methodological flaws included adherence rates, timing of intervention, data collection, measurement consistency and overall study quality. Future clinical trials in this area should also take into consideration the possible side effects/adverse events, the women's individual situation and women's preferences and wishes when designing trials. The importance of providing opportunity for the women to ask questions when seeking advice and support from experts should not be overlooked. The use of antibiotics in the absence of clear indications has no benefit and can lead to harm, not just for the participants, but in the production of antibiotic-resistant strains of the organisms.

Summary of main results

Most studies were small and poor in methodological quality; they were therefore unable to answer the question of effectiveness.

Overall completeness and applicability of evidence

Two studies were stopped prematurely. One study was abandoned after 12 months due to insufficient recruitment of participants, as some women expressed a reluctance to take antibiotics and other women were overwhelmed with challenges they faced as new mothers (Amir 2004). The authors of this study also recognised in retrospect that a feasibility study would have been valuable prior to doing this trial. Livingstone's study also ceased prematurely, due to ethical concerns about the raised incidence of treatment failure and hence symptoms, amongst the participants that did not receive antibiotics (Livingstone 1999). Current evidence is insufficient to provide recommendations for practice of the use of prophylactic antibiotics in the treatment of mastitis. Also, the use of antibiotics in the absence of clear indications has no benefit and can lead to harm, not just for the participants, but in the production of antibiotic-resistant strains of the organisms.

Adherence rates

Adherence rates were reported in three of the five studies. In the smallest study, Amir reported a 100% adherence in the intervention group; as this was small, adherence may be easier to manage (Amir 2004). Svensson's study reported 60% adherence, probably due to unclear patient instructions (Svensson 2004). Despite the larger study size, Sebitloane 2008 only reported a 70% adherence rate. The studies by Amir and Livingstone illustrate the risks experienced with the use of prophylactic antibiotics, problems associated with side effects, and patient compliance and attitudes, which may all affect the adherence and hence study outcome (Amir 2004; Livingstone 1999). Strategies that can be implemented to attempt to improve adherence include extended consultation time

with participants when recruiting participants to explain and reinforce instruction; designing interventions such as tailoring drug regimens to patient lifestyle; frequent follow up when initialising or changing treatment regimes; and the use of reminder calls and alerts to keep participants focused.

Quality of the evidence

Sample size and adequate study power

The size of the studies in this review varied greatly, from 10 to 615 participants. The small numbers of participants in the studies of Amir (10), Livingstone (84, but divided amongst four groups) and Svensson (40), may mean these studies were inadequately powered (Amir 2004; Livingstone 1999; Svensson 2004).

One may question whether some of the interventions used were robust enough to prevent mastitis. Svensson's study was found to have flaws regarding the consumption and preparation of the anti-secretory factor in the cereal (intervention) used (Svensson 2004). The study by De Oliveira provided participants with one education session with a lactation consultant; the intervention may have proven more effective had there been more than a single session and further follow up with the lactation consultant (De Oliveira 2006). This review illustrated problems with complicated interventions requiring many steps or stages, affecting adherence.

Timing of interventions and data collection

The timing of an intervention and data collection need to be relevant to the participants, the condition measured and the outcomes expected. The study by De Oliveira collected data measuring the incidence of mastitis at seven and 30 days within the two groups (De Oliveira 2006). De Oliveira's study may have found different results, had the measures been extended to perhaps three to six months (De Oliveira 2006). Moreover, interventions including education and breastfeeding advice may need to be delivered on an ongoing basis, rather than a single consult.

Measurement consistency

Three studies did not provide a definition of mastitis and the remaining two studies each provide a different definition of mastitis. Moreover, only two studies reported the researchers were blinded to the participant group assignment. None of the studies described who or how the assessments of mastitis were made. We therefore, think it likely that a degree of measurement bias exists in the studies.

Overall study quality

The risk of bias tables suggest that the five studies in this review demonstrate overall poor study quality and design. Poor study quality may at least partially explain why statistically significant interventions to prevent mastitis have yet to be identified in RCTs. This review highlights the need for better planning and design to improve trial quality in this area.

AUTHORS' CONCLUSIONS

Implications for practice

There was insufficient evidence to show effectiveness of any of the interventions.

Implications for research

Until better designed and adequately powered RCTs become available, we will need to rely on clinical studies such as cohort and observational studies when developing breastfeeding policies. Feasibility studies when designing trials are needed to avoid poor adherence and to improve the integrity and intensity of interventions. A universal definition of mastitis would also be helpful. This review

has exemplified that better designed research trials are required to properly evaluate the effectiveness of interventions addressing breastfeeding education, pharmacological treatments and alternative therapies for mastitis in breastfeeding women.

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referee who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Amir 2004

Methods	Randomised controlled trial.
Participants	Breastfeeding postpartum women (N = 10) with cracked nipples colonised with <i>Staphylococcus aureus</i> . Setting: hospitals in Melbourne, Australia. Inclusion criteria: lactating women with <i>Staphylococcus aureus</i> -colonised nipples wishing to breastfeed. Exclusion criteria: cracked nipples that were not colonised with <i>Staphylococcus aureus</i> .
Interventions	Prophylactic antibiotics (flucloxacillin capsules taken for 7 days); N = 5 versus placebo (capsules with glucose powder taken for 7 days); N = 5. Women with a positive nipple culture for <i>Staphylococcus aureus</i> had a follow-up visit at 1 week. Women with negative nipple cultures had telephone follow up at 1 week. All participants had a final telephone interview at 6 weeks.
Outcomes	Mastitis study aborted at 12 months due to poor intervention compliance and lack of eligible participants.
Notes	After 12 months, only 10 of the planned total of 133 women had been randomised to the trial and so the trial was stopped early. The author for this trial was contacted to clarify risks of bias.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	The pharmacist used a random numbers table to label the capsules (placebo or active); sequence was stratified by hospitals in blocks of 10.
Allocation concealment?	Yes	Third party (pharmacist).
Blinding? All outcomes	Yes	Capsules were of identical appearance and so participants and investigators were blinded.
Incomplete outcome data addressed? All outcomes	Yes	2 women (2/10) dropped out of the study as they did not wish to take medications - both women had been allocated to the placebo group.
Free of selective reporting?	Unclear	No evidence of selective reporting.
Free of other bias?	Unclear	Trial stopped early.

De Oliveira 2006

Methods	Randomised controlled trial.
Participants	211 breastfeeding mother-infant pairs. Inclusion criteria: healthy non-twin newborns with birthweight ≥ 2500 g. Exclusion criteria: mother-infant pairs unable to stay together due to a health concern in either the mother or the infant. Setting: Porto Alegre, Brazil (women were recruited from June to November 2003).
Interventions	Breastfeeding education session (30 minutes) with an lactation consultant and an experienced breastfeeding nurse in hospital (N = 74) versus usual care (N = 137). All women received a follow-up home visit at day 7 and day 30.
Outcomes	Measure of exclusive breastfeeding rates, breastfeeding related problems. Measure of mastitis, sore nipples and engorgement.
Notes	Attempts to contact the authors were unsuccessful.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomly assigned using 2 different coloured balls from a bag, 1 colour for the intervention, 1 colour for the control.
Allocation concealment?	Unclear	2 different coloured balls from a bag, 1 colour for the intervention, 1 colour for the control.
Blinding? All outcomes	Unclear	Researchers responsible for assessment blinded to intervention group assignment. Not feasible for participants and clinician.
Incomplete outcome data addressed? All outcomes	Yes	Between 5%-9.9%. The original number of participants in the experimental group and the control group was 74 and 137 respectively. At the time of data analysis there had been a loss of participants in both groups, 3 participants in the experimental group leaving 71 women and 5 women in the control group leaving 132 women.
Free of selective reporting?	Unclear	No evidence of selective reporting
Free of other bias?	Unclear	No apparent evidence of other bias.

Livingstone 1999

Methods	<p>This study trial led basic breastfeeding advice with a combination of antibiotics and topical ointments.</p> <p>Mothers attending breastfeeding clinic for breastfeeding problems, cracked/sore nipples, positive <i>Staphylococcus aureus</i> results.</p> <p>Exclusion criteria: mothers with local or system spread of infection such as cellulitis, ascending lactiferous duct infection or mastitis were excluded.</p>	
Participants	N = 84. Postpartum breastfeeding women with sore or cracked nipples.	
Interventions	<p>4 intervention groups:</p> <p>1. Optimal breastfeeding technique (basic breastfeeding advice) N = 23.</p> <p>2. Topical 2% mupirocin ointment to nipples, N = 25.</p> <p>3. Topical fusidic acid ointment to nipples, N = 17.</p> <p>4. Oral antibiotics - cloxacillin/erythromycin, N = 19.</p>	
Outcomes	Measured nipple symptoms, breast symptoms and mastitis.	
Notes	<p>100% compliance - highly-motivated breastfeeding women. Women that presented with mastitis were excluded from the study. Intention-to-treat not used.</p> <p>This study was stopped prematurely - women who did not receive antibiotic perceived to have a higher rate of mastitis.</p> <p>An attempt to contact this author to clarify findings was unsuccessful.</p>	
<i>Risk of bias</i>		
Item	Authors' judgement	Description
Adequate sequence generation?	Yes	100 tags were alternatively labelled A, B, C, D and placed in an envelope.
Allocation concealment?	Yes	Each case randomly assigned by drawing a tag from the envelope.
Blinding? All outcomes	No	Open unblinded study.
Incomplete outcome data addressed? All outcomes	Yes	No losses reported.
Free of selective reporting?	Unclear	No evidence of selective reporting.
Free of other bias?	Unclear	Trial was stopped early.

Sebitloane 2008

Methods	Randomised controlled trial of women who planned to have caesarean sections and who were HIV infected. This study trial led antibiotics versus placebo.
Participants	N = 615, HIV infected women > 18 years, ≥ 36 weeks' gestation with anticipated vaginal delivery at King Edward VIII and Addington Hospital in Durban, South Africa between February 2003 and May 2005. 675 delivered at the hospitals in the study and were eligible for randomisation. 60 had a planned caesarean section and were excluded. 305 were randomised and received cefoxitin and 310 were randomly assigned the placebo. Following this, a further 92 women from the intervention group and 99 from the placebo group were excluded because they had an emergency caesarean delivery.
Interventions	2 gm dose of cefoxitin intravenously over 20 minutes during active labour versus a water placebo administered over the same period of time.
Outcomes	Of the 213 women assigned randomly to the cefoxitin group, 182 (85%) returned for the follow-up evaluation at 1 week and 184 (86%) returned at 2 weeks. Of the 212 women assigned the placebo, 180 (85%) returned for the follow up at 1 week and 178 (84%) returned at the 2 week for follow up.
Notes	Clinicians blinded to intervention. Women were excluded if they had an emergency caesarean delivery after randomisation. The randomised groups were comparable with regards age, parity, gestational age at delivery and most baseline haematology. An attempt to contact this author to clarify findings was unsuccessful.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Computer generated by statistician. Syringes labelled D001-D686; participants were given the drug during labour according to the next available number.
Allocation concealment?	Yes	The statistician generated a computer-based allocation of each study numbered 1-686 into either group 1 or 2 which represented either cefoxitin or placebo. Only the pharmacist was aware of the drug code for the duration of the study.
Blinding? All outcomes	Unclear	Blinded to clinicians.
Incomplete outcome data addressed? All outcomes	Unclear	Incomplete outcome data > 20%. The original number of participants in the study was 716, of which 675 delivered within the study premises. 60 of these women were not randomised. Finally 615 women were

Sebitloane 2008 (Continued)

		randomised, with 305 women in the experimental group and 310 in the control group. The 1-week follow up resulted in 182 participants in the experimental group and 180 in the control group. At the 2-week follow up there were 184 in the experimental group and 178 in the control group.
Free of selective reporting?	Unclear	No evidence of selective reporting
Free of other bias?	Unclear	No apparent evidence of other bias.

Svensson 2004

Methods	This study trial led the use of anti-secretory factor (AF) in cereal to prevent mastitis. Data collected from April to August 2002. All mothers were Swedish or raised in Sweden. Duration of follow up 5 weeks.
Participants	N = 40 postpartum breastfeeding women that had normal deliveries and have healthy full term infants, were randomly divided into 2 groups. Participants were breastfeeding or intended to breastfeed.
Interventions	Anti-secretory factor in cereal versus similar cereal without the AF. Experimental group N = 12, control group N = 16 (11 mothers dropped out and one mother failed to give a milk sample from the control group).
Outcomes	Incidence of mastitis between groups.
Notes	Participants requested to eat 50 g of cereal for a period of 5 weeks. Duration of follow up was 5 weeks. No difference between the groups, regarding background, obstetric data, age, education, parity, type of anaesthesia used during the delivery, child sex and birth rate. Loss of participants to follow up > 20%. To date, attempts to contact the authors have been unsuccessful.

Risk of bias

Item	Authors' judgement	Description
Adequate sequence generation?	Yes	Randomly assigned (sealed envelopes that were opened consecutively) to 1 of 2 groups. (further information not available at this stage, unable to contact the author).
Allocation concealment?	Unclear	Sealed envelopes that were opened consecutively.

Svensson 2004 (Continued)

Blinding? All outcomes	Yes	Blinding to participants, cereal used looked the same. Researchers and participants blinded to which cereal was allocated. Randomising sequence concealed until data were collected and laboratory analysis was performed.
Incomplete outcome data addressed? All outcomes	Yes	Incomplete outcome data > 20%. The original number of participants in the study was 40. 11 of these participants dropped out in the first 2 weeks. 7 mothers in the experimental group and 3 in the control group. 1 mother was excluded because of incorrect compliance of the intervention. The final number for the experimental group was 12 mothers and 17 for the control group. 1 of the mothers in the control group failed to provide a milk sample at the end of the study. Final data analysis was on 12 mothers from the experimental group and 17 from the control group.
Free of selective reporting?	Unclear	No evidence of selective reporting
Free of other bias?	Unclear	No apparent evidence of other bias.

GP: general practitioner

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Blaikley 1953	This study is not a randomised controlled trial and does not meet the requirements necessary for random allocation, concealment or blinding.
Bystrova 2007	This is not a trial of mastitis prevention. It is an RCT on the effect of different postnatal ward practices on lactation performance.
Centuori 1999	This is not a trial of mastitis prevention. It is an RCT on treating sore nipples.
Evans 1995	This study is not a randomised controlled trial and does not meet the requirements necessary for random allocation, concealment or blinding.

(Continued)

Filteau 1999	This is not a trial of mastitis prevention. It is an RCT of postpartum maternal vitamin A supplementation.
Forster 2004	This is an RCT of strategies to increase breastfeeding initiation and duration.
Frank 1987	This is not a trial of mastitis prevention. It is an RCT of discharge packs and counselling to increase breastfeeding duration.
Gomo 2003	This is a micronutrient RCT looking at preventing 'subclinical' mastitis.
Gunn 1998	This trial did not evaluate interventions for preventing mastitis - it is a trial comparing early postnatal check up with a GP (at one week) with the usual 6 week check up.
Hager 1996	Treatment of mastitis, not prevention.
Harvey 1988	This is an RCT/quasi-RCT for preventing sore nipples.
Herd 1986	This is an RCT for treating nipple trauma.
Homer 2001	This is a continuity of care RCT.
Kramer 2001	This is an RCT of breastfeeding promotion.
Kvist 2004	This is a treatment trial.
Kvist 2007	This is a treatment trial.
Lawlor-Smith 1997	This is not an RCT.
Lumley 2006	This is an RCT of resources, information and support for postpartum women.
Luttkus 1997	This is an RCT of antibiotic prophylaxis for caesarean section.
McLachlan 1991	This is an RCT of ultrasound treatment for breast engorgement.
Meah 2001	This is not an RCT. It is a letter re Kramer 2001 .
Neifert 1990	This is not an RCT.
Nicholson 1985	This is an RCT of treating cracked nipples.
Nicholson 1993	This is not an RCT.
Nikodem 1993	This is an RCT for preventing breast engorgement.
Phillips 1975	This is an RCT for preventing breast engorgement.
Roberts 1995	This is an RCT for treating breast engorgement.

(Continued)

Roberts 1998	This is an RCT for treating breast engorgement.
Schurz 1978	This is a quasi-randomised trial (women were allocated by the first letter of their surname).
Swift 2003	This is an RCT of lactation suppression (breast binding).
Thomsen 1984	Treatment of mastitis, not prevention.
Waldenstrom 1994	This trial did not evaluate interventions for preventing mastitis - it is an RCT comparing birth centre care versus usual obstetric care.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Gensch 2006

Methods	Randomised controlled trial.
Participants	45 lactating mothers.
Interventions	Lanolin cream versus breast milk.
Outcomes	Mastitis observed in breast milk group.
Notes	Author has been contacted with regards this study. It is currently with a review committee and is not available. We will reassess this study at a later date

Characteristics of ongoing studies *[ordered by study ID]*

Crepinsek 2008

Trial name or title	'Self-management versus usual care for the treatment of mastitis following childbirth: a randomised controlled trial'.
Methods	Mastitis following childbirth.
Participants	Breastfeeding women following childbirth at the Gold Coast Hospital, Queensland, Australia.
Interventions	Breastfeeding and mastitis education tool (pamphlet format - flow chart). N = 680 women, randomly allocated into the intervention group or the control group. Random allocation using computer-generated numbers. Opaque sealed envelopes used to conceal the intervention and control when allocated to participants following recruitment into the study. Study blinded to participants, clinician and outcome assessor until all participants are recruited and 6-month follow up is completed.

Crepinsek 2008 (Continued)

Outcomes	Measure the incidence of mastitis in this sample of women over a period of 6 months following the trial of the intervention versus the usual care of the women postpartum. Measure the length of exclusive and any breastfeeding in this sample of women over a period of 6 months following the trial of the intervention versus the usual care of the women postpartum.
Starting date	January 2008.
Contact information	Mrs Maree Crepinsek PHCRED, HSM Bond University Gold Coast QLD Australia PH: 07 5595 4494 Email: mcrepins@bond.edu.au
Notes	Recruitment of participants temporarily ceased in October 2008.

DATA AND ANALYSES

Comparison 1. Antibiotic versus no antibiotic

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mastitis	3		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Antibiotic versus no antibiotic	3	471	Risk Ratio (M-H, Fixed, 95% CI)	0.43 [0.11, 1.61]
1.2 Antibiotic versus placebo	2	387	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.15, 6.68]
1.3 Antibiotic versus mupirocin	1	44	Risk Ratio (M-H, Fixed, 95% CI)	0.44 [0.05, 3.89]
1.4 Antibiotic versus fusidic acid	1	36	Risk Ratio (M-H, Fixed, 95% CI)	0.22 [0.03, 1.81]
1.5 Antibiotic versus breastfeeding advice	1	42	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.02, 1.28]

Comparison 2. Breastfeeding education (specialist) versus usual care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mastitis	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 at hospital discharge	1	211	Risk Ratio (M-H, Fixed, 95% CI)	Not estimable
1.2 at 7 days	1	210	Risk Ratio (M-H, Fixed, 95% CI)	3.75 [0.35, 40.70]
1.3 at 30 days	1	203	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.17, 4.95]
2 Sore nipples	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 at hospital discharge	1	211	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.72, 1.36]
2.2 at 7 days	1	210	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.66, 1.22]
2.3 at 30 days	1	203	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.36, 2.37]
3 Breast engorgement	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 at hospital discharge	1	211	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.03, 14.87]
3.2 at 7 days	1	210	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.71, 1.53]
3.3 at 30 days	1	203	Risk Ratio (M-H, Fixed, 95% CI)	1.04 [0.73, 1.49]
4 Exclusive breastfeeding	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 at 7 days	1	210	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.90, 1.18]
4.2 at 30 days	1	203	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.68, 1.14]
5 Breastfeeding problems, mean per mother	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
5.1 at hospital discharge	1	211	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.27, 0.67]
5.2 at 30 days	1	211	Mean Difference (IV, Fixed, 95% CI)	-0.20 [-0.61, 0.21]

Comparison 3. Anti-secretory factor in cereal versus standard cereal

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mastitis	1	29	Risk Ratio (M-H, Fixed, 95% CI)	0.24 [0.03, 1.72]
2 Mastitis recurrence	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 First recurrence	1	29	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 3.51]
2.2 Second recurrence	1	29	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.02, 10.45]

Comparison 4. Mupirocin ointment versus breastfeeding advice alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mastitis	1	48	Risk Ratio (M-H, Fixed, 95% CI)	0.39 [0.12, 1.35]

Comparison 5. Fusidic acid ointment versus breastfeeding advice alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mastitis	1	40	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.27, 2.22]

Comparison 6. Mupirocin ointment+BF advice versus fusidic acid ointment+BF advice

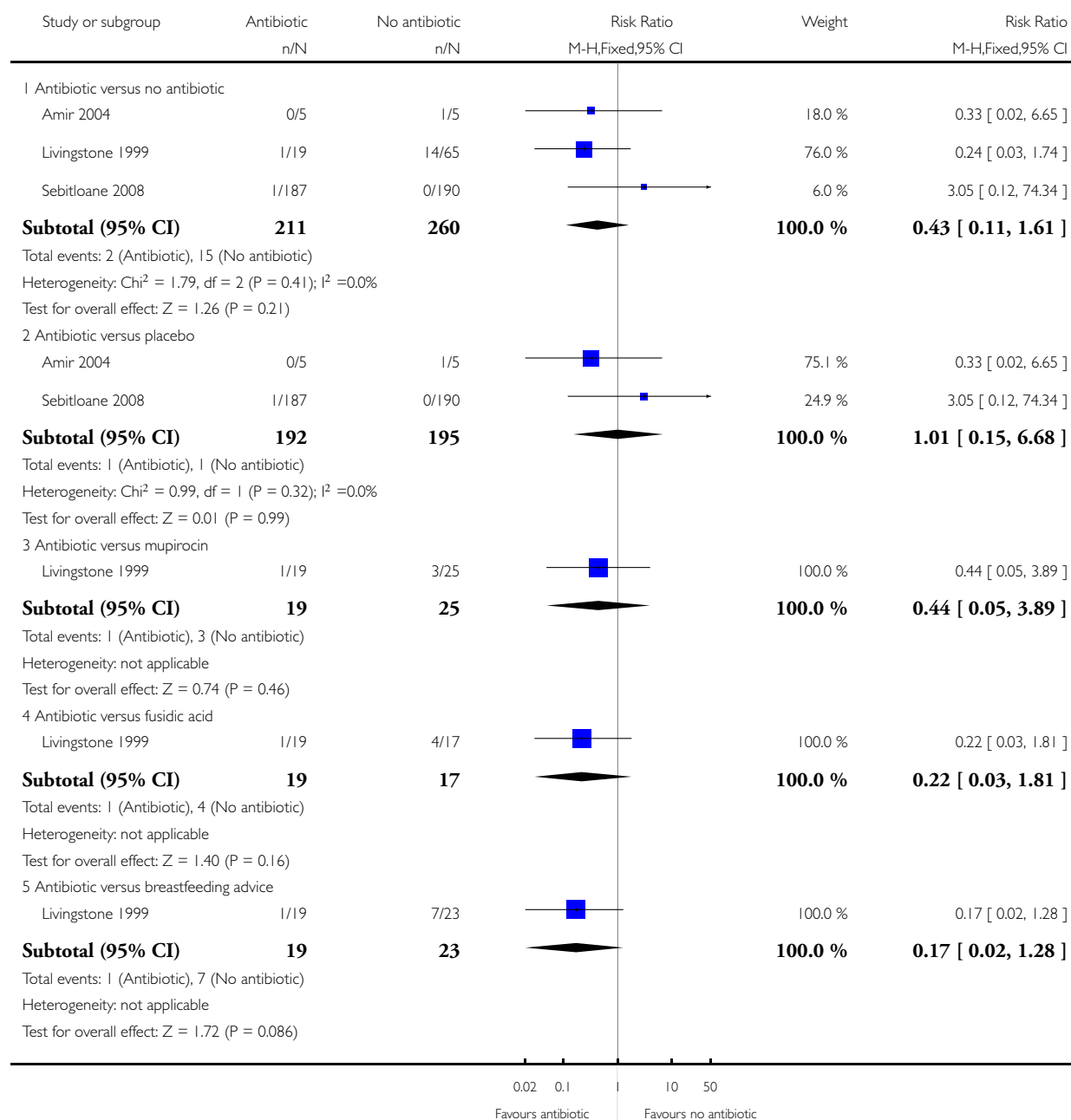
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Mastitis	1	42	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.13, 2.00]

Analysis 1.1. Comparison 1 Antibiotic versus no antibiotic, Outcome 1 Mastitis.

Review: Interventions for preventing mastitis after childbirth

Comparison: 1 Antibiotic versus no antibiotic

Outcome: 1 Mastitis

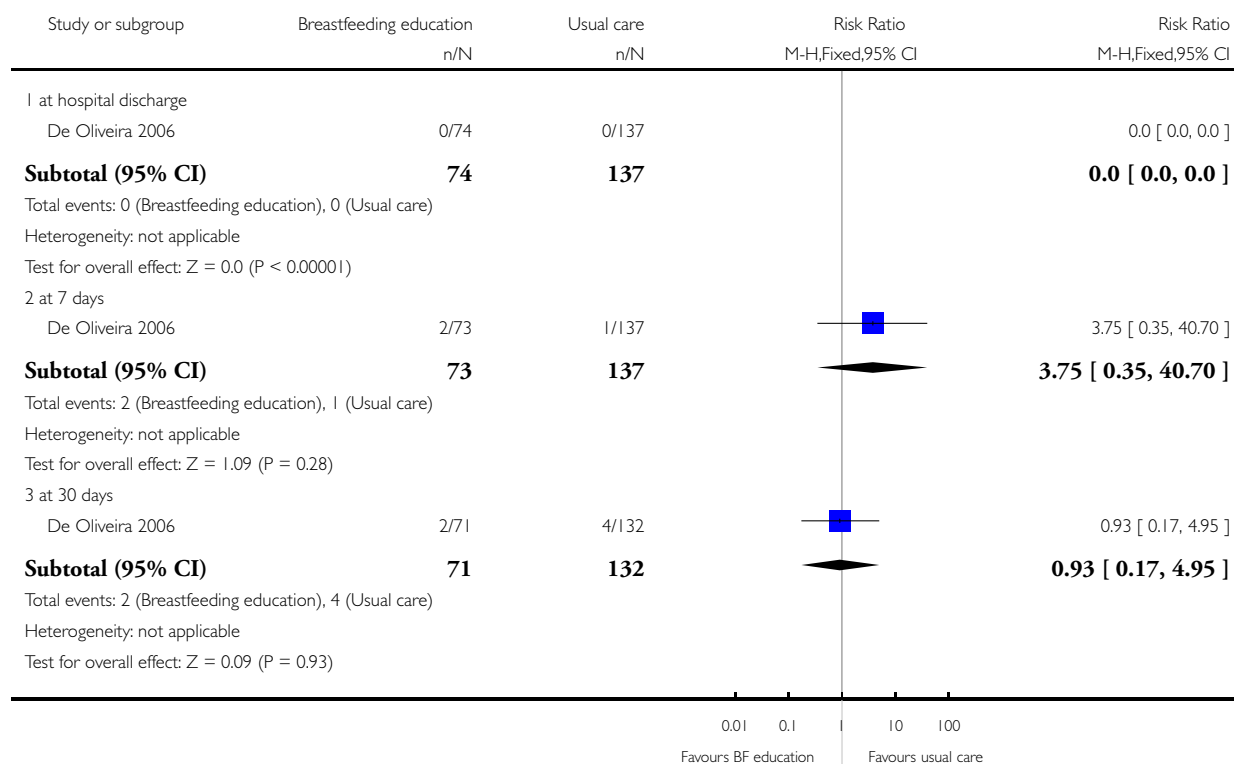


Analysis 2.1. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 1 Mastitis.

Review: Interventions for preventing mastitis after childbirth

Comparison: 2 Breastfeeding education (specialist) versus usual care

Outcome: 1 Mastitis

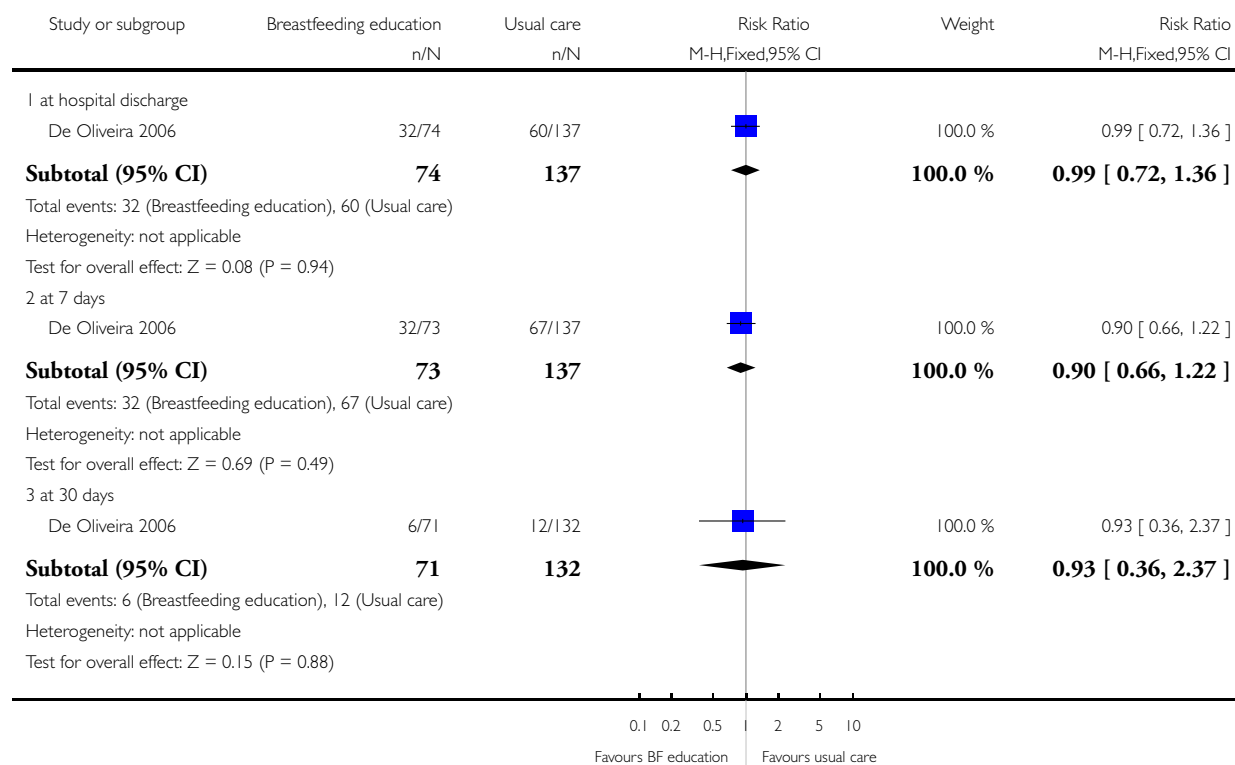


Analysis 2.2. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 2 Sore nipples.

Review: Interventions for preventing mastitis after childbirth

Comparison: 2 Breastfeeding education (specialist) versus usual care

Outcome: 2 Sore nipples

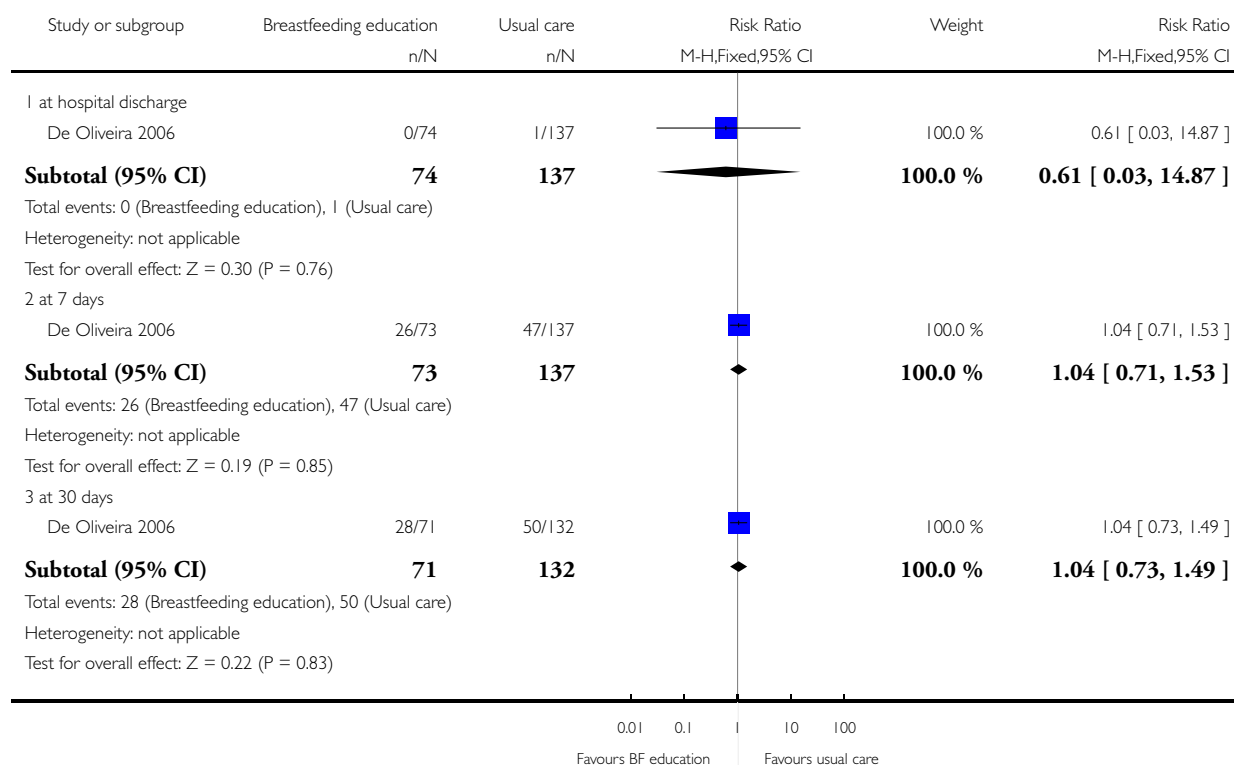


Analysis 2.3. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 3 Breast engorgement.

Review: Interventions for preventing mastitis after childbirth

Comparison: 2 Breastfeeding education (specialist) versus usual care

Outcome: 3 Breast engorgement

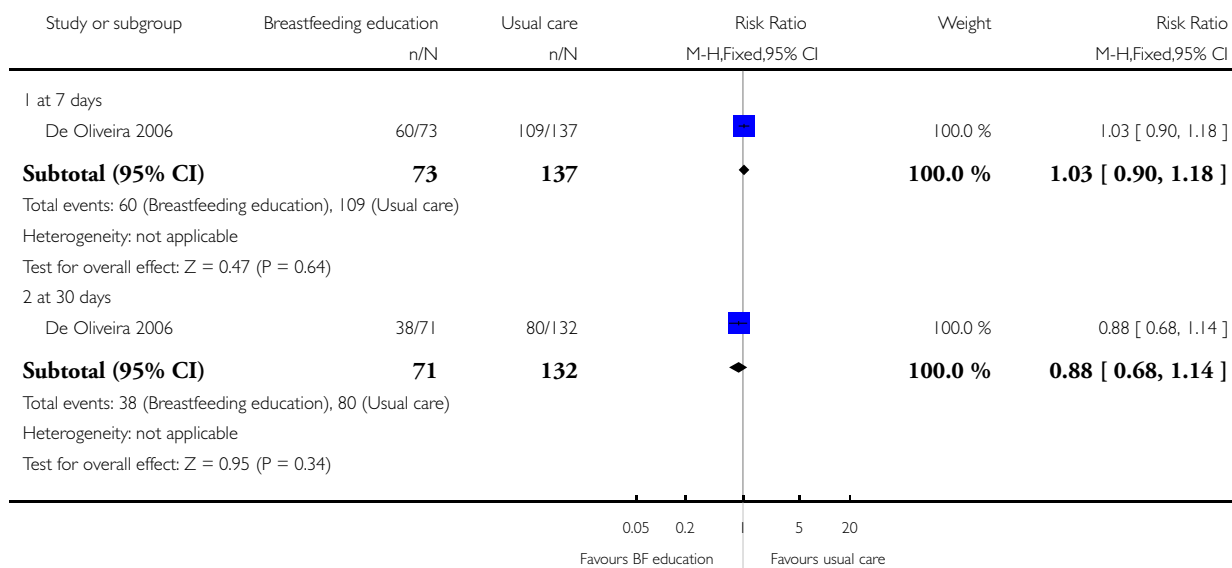


Analysis 2.4. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 4 Exclusive breastfeeding.

Review: Interventions for preventing mastitis after childbirth

Comparison: 2 Breastfeeding education (specialist) versus usual care

Outcome: 4 Exclusive breastfeeding

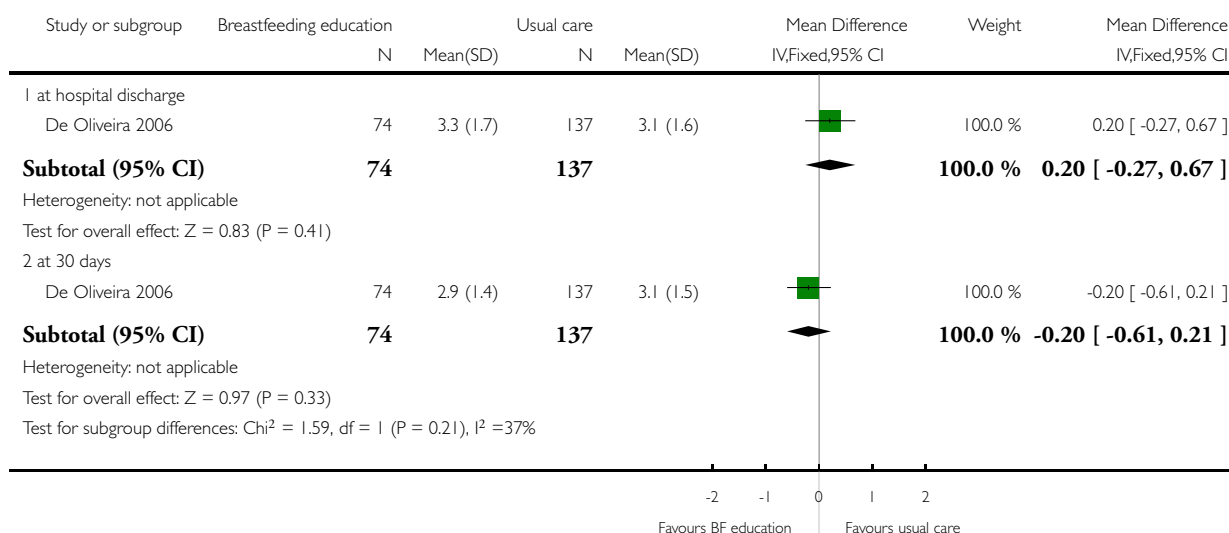


Analysis 2.5. Comparison 2 Breastfeeding education (specialist) versus usual care, Outcome 5 Breastfeeding problems, mean per mother.

Review: Interventions for preventing mastitis after childbirth

Comparison: 2 Breastfeeding education (specialist) versus usual care

Outcome: 5 Breastfeeding problems, mean per mother

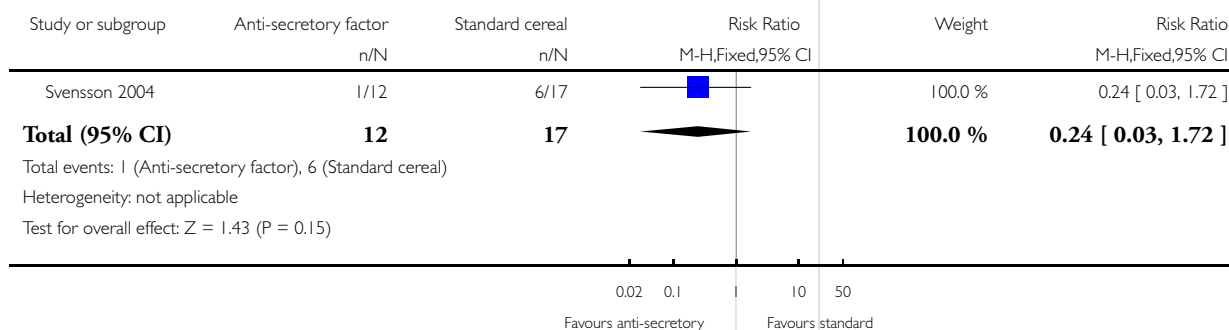


Analysis 3.1. Comparison 3 Anti-secretory factor in cereal versus standard cereal, Outcome 1 Mastitis.

Review: Interventions for preventing mastitis after childbirth

Comparison: 3 Anti-secretory factor in cereal versus standard cereal

Outcome: 1 Mastitis

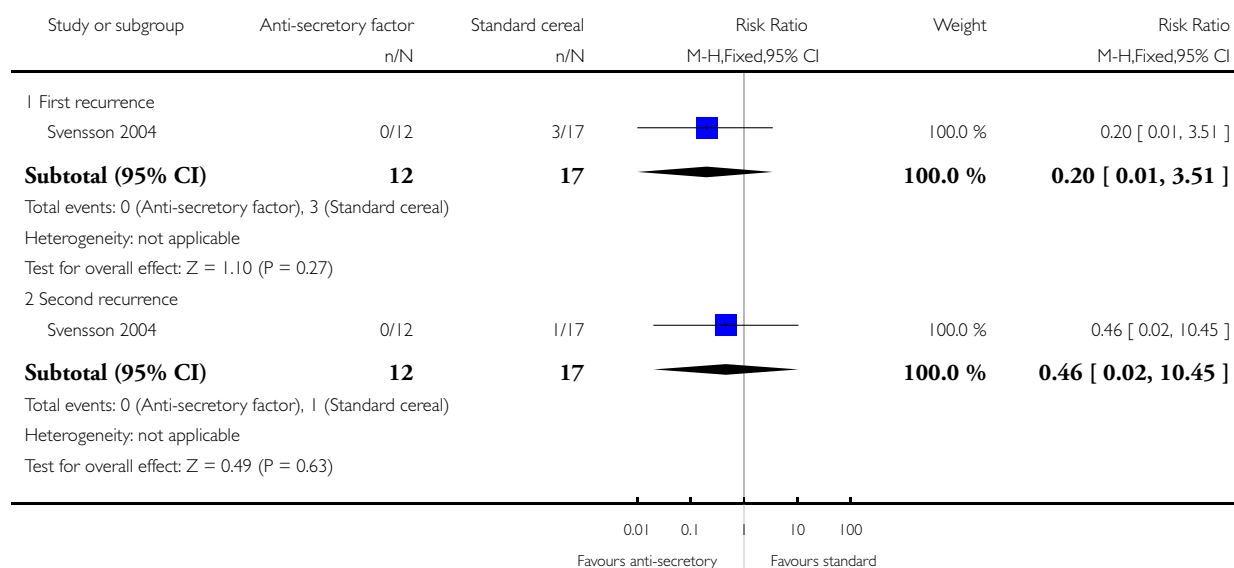


Analysis 3.2. Comparison 3 Anti-secretory factor in cereal versus standard cereal, Outcome 2 Mastitis recurrence.

Review: Interventions for preventing mastitis after childbirth

Comparison: 3 Anti-secretory factor in cereal versus standard cereal

Outcome: 2 Mastitis recurrence

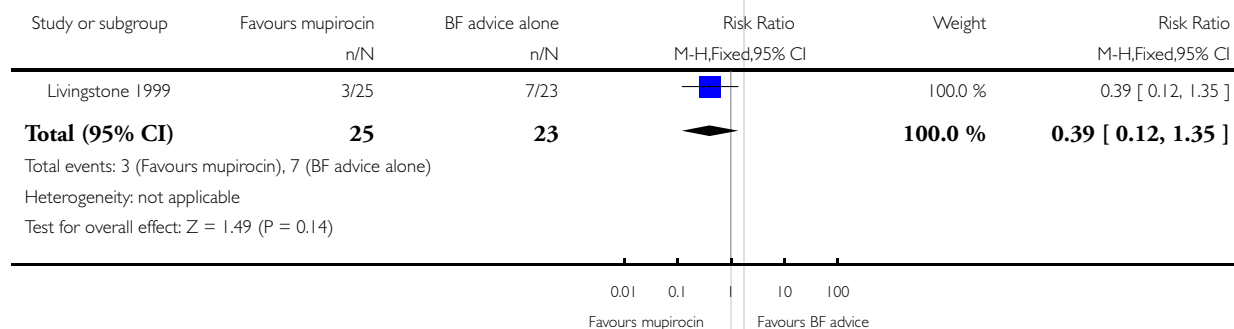


Analysis 4.1. Comparison 4 Mupirocin ointment versus breastfeeding advice alone, Outcome 1 Mastitis.

Review: Interventions for preventing mastitis after childbirth

Comparison: 4 Mupirocin ointment versus breastfeeding advice alone

Outcome: 1 Mastitis

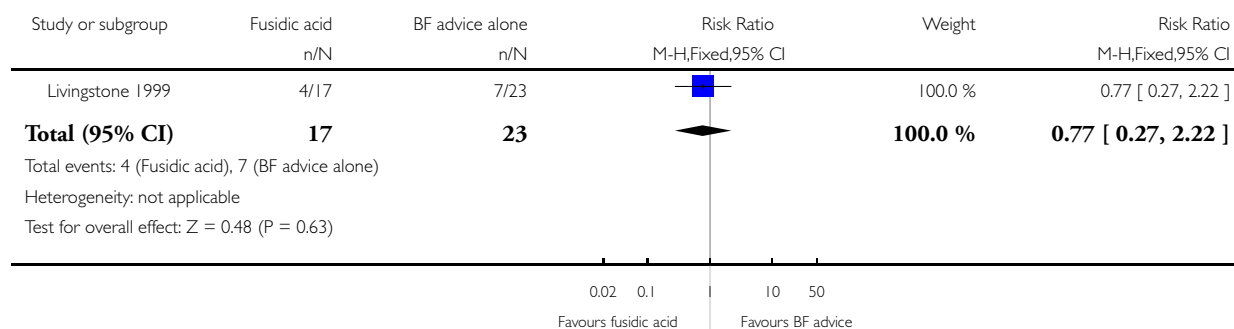


Analysis 5.1. Comparison 5 Fusidic acid ointment versus breastfeeding advice alone, Outcome 1 Mastitis.

Review: Interventions for preventing mastitis after childbirth

Comparison: 5 Fusidic acid ointment versus breastfeeding advice alone

Outcome: 1 Mastitis

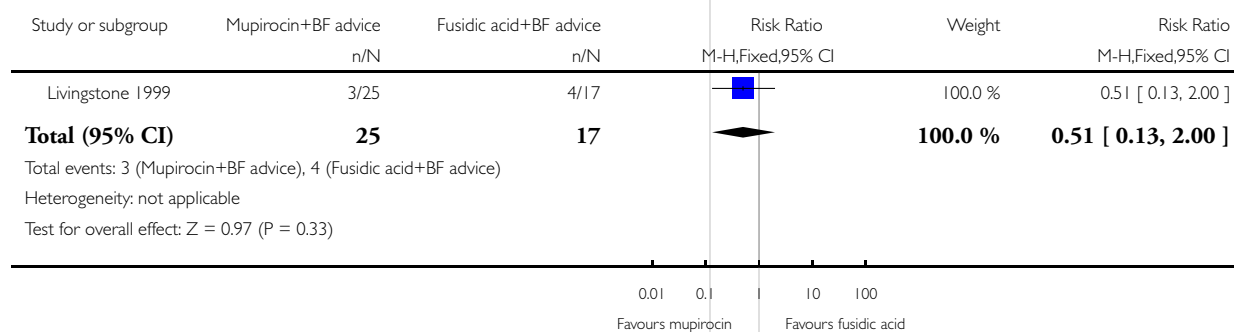


Analysis 6.1. Comparison 6 Mupirocin ointment+BF advice versus fusidic acid ointment+BF advice, Outcome 1 Mastitis.

Review: Interventions for preventing mastitis after childbirth

Comparison: 6 Mupirocin ointment+BF advice versus fusidic acid ointment+BF advice

Outcome: 1 Mastitis



APPENDICES

Appendix I. Search strategies

Searches designed and conducted by Keryl Michener

CENTRAL (*The Cochrane Library 2009, Issue 4*)

- #1 MeSH descriptor Mastitis explode all trees
- #2 mastitis
- #3 MeSH descriptor Infection explode all trees
- #4 infection
- #5 MeSH descriptor Abscess explode all trees
- #6 abscess*
- #7 MeSH descriptor Inflammation explode all trees
- #8 inflam*
- #9 MeSH descriptor Sepsis explode all trees
- #10 septic*emia
- #11 engorg*
- #12 (#1 OR #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #11)
- #13 MeSH descriptor Breast Feeding explode all trees
- #14 breast*feed
- #15 MeSH descriptor Milk, Human
- #16 nursing NEAR/5 mother*
- #17 (#13 or #14 or #15 or #16)
- #18 (#12 and #17)

MEDLINE (Ovid) (1950 to November 2009)

- 1. breast?feeding.mp. or exp Breast Feeding/
- 2. exp Lactation/ or lactating.mp.
- 3. exp Milk, human/
- 4. (nursing adj5 mother\$).mp.
- 5. or/1-4
- 6. exp Infection/ or infection\$.mp.
- 7. exp Abscess/ or abscess\$.mp.
- 8. septic?emia.mp. or exp Sepsis/
- 9. engorg\$.mp.
- 10. inflam\$.mp.
- 11. exp Mastitis/ or mastitis.mp.
- 12. or/6-11
- 13. 5 and 12
- 14. randomized controlled trial.pt.
- 15. controlled clinical trial.pt.
- 16. randomized.ab.
- 17. placebo.ab.
- 18. drug therapy.fs.
- 19. randomly.ab.
- 20. trial.ab.
- 21. groups.ab.
- 22. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21
- 23. 13 and 22
- 24 humans.sh.
- 25. 23 and 24

EMBASE (Science Direct) (1974 to November 2009)

- #1. 'mastitis'/exp OR mastitis:ti,ab
- #2. 'infection'/ OR infection*:ti,ab

- #3. 'abscess'/exp OR abscess*:ti,ab
- #4. 'septicemia'/exp OR septic*emia:ti,ab OR sepsis:ti,ab
- #5. 'breast engorgement'/exp OR engorge*:ti,ab
- #6. inflamm*:ti,ab
- #7. 'breast feeding'/exp OR breast*feeding:ti,ab
- #8. 'lactation'/exp OR lactat*:ti,ab
- #9. 'breast milk'/exp OR 'breast milk':ti,ab
- #10. 'nursing mother':ti,ab
- #11. 'nursing mothers':ti,ab
- #12. #1 or #2 or #3 or #4 or #5 or #6
- #13. #7 or #8 or #9 or #10 or #11
- #14. #12 and #13

We combined this with the following terms for identifying trials (free-text terms: random*; crossover*; cross over; placebo*; 'double blind*'; 'singl blind'; assign' allocate*; volunteer*; and index terms, known as Emtree terms: crossover-procedure; double-blind procedure; randomized controlled trial; single-blind procedure. (adapted from [Lefebvre 2008](#)).

then added NOT ((**animal:de** OR **nonhuman:de**) NOT (**human:de** AND (**animal:de** OR **nonhuman:de**)))

CINAHL (1981 to November 2009)

- S1 ("mastitis") or (MH "Mastitis")
- S2 (MH "Breast Feeding+") or breast fe* or breastfe*
- S3 (MH "Lactation") or lactat*
- S4 ("human milk") or (MH "Milk, Human")
- S5 nursing N5 mother*
- S6 (MH "Infection+") or infect*
- S7 (MH "Abscess+") or abscess*
- S8 (MH "Sepsis") or septic?emia
- S9 engorg* or inflam*
- S10 S2 or S3 or S4 or S5
- S11 S6 or S7 or S8 or S9
- S12 (S10 and S11)
- S13 S12 or S1

Combined with adapted version of [Wong 2006](#) filter

MIDIRS (the Maternity Infant Database) (Ovid) (1971 to November 2009),

IPA (Ovid) (1970 to November 2009),

AMED (Ovid) (1985 to November 2009)

Searched using the same strategy for MEDLINE

LILACS (1982 to November 2009)

((breastfe\$ OR puerp\$ OR mastitis) OR breast-feeding (subject identifier))

AND

(trial\$ or random\$))

OR (mastitis AND NOT cattle))

HISTORY

Protocol first published: Issue 3, 2008

Review first published: Issue 8, 2010

CONTRIBUTIONS OF AUTHORS

Maree Crepinsek is the primary author as well as the contact author. The conception, design, and co-ordination of the review have been done by Maree Crepinsek. Maree has also provided a clinical perspective for the review, as well as writing the review in Review Manager. Dr Neil Smart has provided support as a co-author, providing general advice on the writing both the protocol and review. Maree Crepinsek and Dr Neil Smart independently reviewed all articles found in the search, initially by title and abstract. Maree Crepinsek and Dr Neil Smart then reviewed the full text of articles selected for inclusion or exclusion into the review. Linda Crowe is the second author who provides a clinical perspective and general advice on the review. Maree Crepinsek and Linda Crowe independently extracted the data from the selected articles for analysis. Keryl Michener has provided support as a librarian writing search strategies for the additional searching, carrying out those searches and locating papers that have been used as background research evidence. All authors have been involved in editing the drafts of this review prior to submission.

DECLARATIONS OF INTEREST

One of the authors of the protocol, Maree Crepinsek, is the primary investigator on a RCT that commenced in January 2008 titled 'Self-management versus usual care for the treatment of mastitis following childbirth: a randomised controlled trial' ([Crepinsek 2008](#))

SOURCES OF SUPPORT

Internal sources

- PHCRED Faculty of Health Science and Medicine Bond University, Queensland, Australia.

External sources

- Herston Health Science Library, University of Queensland, Brisbane, Australia.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have deleted the part of the secondary objective related to pain, as pain was not listed as an outcome in the protocol.

We have searched additional databases, including CINAHL, AMED, IPA and MIDIRS, which we did not include in the protocol.

Breastfeeding in an urban population

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